NICNAS DIRECTOR'S DECISIONS ON REQUESTS FOR VARIATION OF THE DRAFT PHOSLOCK SECONDARY NOTIFICATION ASSESSMENT (SNA) REPORT

1. PHOSLOCK WATER SOLUTIONS LIMITED.

Request 1.1

Page vii, second paragraph

"In addition, a number of dead fish were found floating in the Deep Creek Reservoir in southern New South Wales (NSW) following the application of Phoslock ™."

Suggested change:

"In addition, a number of dead fish were found floating in the Deep Creek Reservoir in southern New South Wales (NSW) following an abnormal application of Phoslock™ in conjunction with other agents."

Reason:

- Application rate at Deep Creek was three times the recommended dose and would not be considered a 'normal' application of Phoslock™.
- A large amount of soda ash was applied to the water body and not just Phoslock™.
- It is unclear if the death of fish found floating on the reservoir water was due to the aquatic toxicity of Phoslock™, a pH change in the water as a result of soda ash application, or some other factor.

Decision 1.1

Variation partially approved.

NICNAS Response 1.1

Statement to read as: "In addition, a number of dead fish were found floating in the Deep Creek Reservoir in southern New South Wales (NSW) following an application of Phoslock™, that was atypical in relation to both dose and addition of other agents."

Request 1.2

Page vii, last paragraph

"... and studies using soluble lanthanum salts. In humans and animals, lanthanum from lanthanum carbonate..."

Suggested change:

"... and studies using soluble lanthanum salts. Regardless of the source of lanthanum the systemic toxicological effects are mediated by lanthanum ions (i.e. soluble lanthanum). In humans and animals, lanthanum from lanthanum carbonate..."

Reason:

- The insertion of the new sentence provides contextual information important for understanding the toxicological data of different lanthanum compounds and its relevance to measured lanthanum in treated water bodies.

Decision 1.2

Variation approved.

NICNAS Response 1.2

Additional text will be included in the report.

Request 1.3

Page vii& viii, last & first sentence

"Bioavailable lanthanum is distributed and accumulates in body tissues, especially in the liver and stomach (animals) and bone (animals and humans)."

Suggested change:

"After repeated oral administration lanthanum high concentrations retained in the stomach (animals) and absorbed lanthanum accumulates in the liver (animals) and bone (animals and humans)".

Reason:

- Accumulation in the stomach, and elsewhere in the GIT, is not from absorbed lanthanum. The sentence has therefore been rearranged to reflect this.

Decision 1.3

Variation partially approved.

NICNAS Response 1.3

Text to read: "After repeated oral administration of lanthanum, the majority remains in the gastrointestinal tract (animals) and absorbed lanthanum accumulates in the liver (animals) and bone (animals and humans)."

Request 1.4

Page viii, third paragraph

"Repeated oral exposure to lanthanum chloride in the rat, mouse, and dog, as well as supplemental intravenous studies on lanthanum chloride is associated consistently with adverse effects on the stomach and liver."

Suggested change:

"Repeated oral exposure to lanthanum chloride in the rat, mouse, and dog is consistently associated with adverse effects on the stomach and liver. Liver toxicity is also observed after repeated intravenous administration to dogs."

Reason:

- The current data set does not show stomach effects associated with i.v. administration. Hence the rearrangement of the information.

Decision 1.4

Variation approved.

NICNAS Response 1.4

Text will be amended accordingly.

Request 1.5

Page viii, fourth paragraph

"Several in vitro (lanthanum carbonate) and in vitro (lanthanum carbonate and lanthanum chloride) genotoxicity studies are available and, despite a single equivocal result in vitro, the weight of evidence indicates that lanthanum is unlikely to be genotoxic in vitro."

Suggested change:

"Several in vitro (lanthanum carbonate) and in vitro (lanthanum carbonate and lanthanum chloride) genotoxicity studies are available. The weight of evidence indicates that lanthanum is unlikely to be genotoxic in vitro."

Reason:

- It is inappropriate to emphasise a single equivocal data point. It is not necessary when the WOE speaks for itself. It has therefore been deleted.

Decision 1.5

Variation approved.

NICNAS Response 1.5
Amended text will be included in the report.

Request 1.6
Page viii, fifth paragraph
"... are observed with a lowest observed adverse effect level (LOAEL) of 2 mg/kg bw/day and NOAEL of 0.1 mg/kg bw/day. This NOAEL is taken forward in the estimation of Phoslock™ risks."
Suggested change:
Clarification required; the above implies 0.1 mg/kg/d is to be used throughout the risk assessment. In fact 2 mg/kg/d is used for adults, there is however no indication how this value was derived.

Decision 1.6
Variation approved.

NICNAS Response 1.6
The sentence will be revised as: "... are observed with a NOAEL of 2 and 0.1 mg/kg bw/day for adults and children. These NOAELs are taken forward in the estimation of Phoslock™ risks."

Request 1.7
Page viii, Public exposure and health risk, first paragraph
"... source of exposure to consumers (adults and children), and thus the risk, is likely to be oral through ingestion of water containing soluble lanthanum. However, dermal and ocular exposure may also occur by contact during bathing and swimming."
Suggested change:
"... source of exposure to consumers (adults and children), and thus the risk, is likely to be oral through ingestion of tap water containing soluble lanthanum. However, dermal and ocular exposure may also occur by contact during bathing and swimming, particularly in the treated source waters."
Reason:
- The insertion of 'tap' provides clarity for how the general public might be exposed.

Decision 1.7
Variation partially approved.

NICNAS Response 1.7
Amended text will be incorporated to read as: "... source of exposure to consumers (adults and children), and thus the risk, is likely to be oral through ingestion of tap water containing soluble lanthanum. However, dermal, ocular, and accidental ingestion exposure may also occur by contact during bathing and swimming, particularly in the treated source waters."

Request 1.8
Page ix, first paragraph
"The risk of chronic health effects from drinking water in various modelled scenarios is variable, but it is also of concern that lanthanum has been shown to accumulate in the liver (animals) and bone (in animals and humans) and that the extent and potential adverse consequences of lanthanum accumulation in humans is unknown".
Suggested change: *Delete*
Reasons:
- The sentence is confusing and repeats what is on pages vii and viii.
- It is also arguable that the consequences of lanthanum in humans are not totally unknown. There is a wealth of information from clinical use of lanthanum carbonate.

Decision 1.8
Variation not approved.

NICNAS Response 1.8
Sentence will be amended to read as: "The risk of chronic health effects from lanthanum in drinking water is a potential concern since lanthanum has been shown to accumulate in the liver (animals) and bone (in animals and humans) and that the extent and potential adverse consequences of lanthanum accumulation in humans is unknown".

Request 1.9
Page ix, second paragraph
"The NOAEL of 0.1 mg/kg bw/day is used in this report is consistent with the NOAEL utilised by the National Health and Medical Research Council (NHMRC) in deriving for a guideline value for lanthanum in the then proposed Australian Drinking Water Guidelines (ADWG) (NHMRC, 2010). The NOAEL determined by NICNAS and the NHMRC reached the same conclusions on potential impacts of lanthanum on neurotoxicity and neurobehavioural effects. The lanthanum fact sheet, as part of the then proposed ADWG for consultation in 2010, converted the NOAEL to a drinking water guideline value of 0.002 mg/L using a standardised approach. The concentration is used as an example scenario of the impact of a controlled concentration of lanthanum in drinking water, based on the assumptions that underpinned the proposed guideline. This guideline has not been endorsed by the NHMRC."
Suggested change:
"The NOAEL of 0.1 mg/kg bw/day used in this report is consistent with the NOAEL utilised by the National Health and Medical Research Council (NHMRC) in deriving a guideline value for lanthanum in the then proposed Australian Drinking Water Guidelines (ADWG) (NHMRC, 2010). NICNAS and the NHMRC reached the same conclusions regarding the potential neurotoxic and neurobehavioural effects of soluble lanthanum. Converting the NOAEL to a drinking water guideline value using a standardised approach gives a value of 0.002 mg/L. This concentration has not been endorsed by the NHMRC but is used in an example risk assessment to evaluate the possible health impacts for a scenario in which the concentration of lanthanum in tap water is considered to be well controlled. Another scenario in which it was assumed the lanthanum concentration in drinking water was not well controlled (0.03 mg/L) has also been evaluated."
Reason:

- Grammar in the paragraph was incorrect.
- The references to the draft NHMRC drinking water guideline were excessive.
- The paragraph did contain all the information relevant to the risk assessment scenarios.
- The revision makes it clear the risk assessment scenarios and the water concentrations in them are illustrations for the purposes of assessing possible health effects in 'what if' type exposure scenarios.

Decision 1.9
Variation approved.

NICNAS Response 1.9
The revision will be incorporated in the report with a minor change to the last sentence to read as: "... Another scenario in which it was assumed the lanthanum concentration in drinking water was not well controlled (0.033 mg/L) has also been evaluated."

Request 1.10
Page ix, third paragraph (dot points)
"The modelled drinking water scenarios include drinking water intake where:

- *a control on the level of lanthanum existed, for which the margin of exposure (MOE) was acceptable for both adults and children; and*
- *the lanthanum levels are well above a controlled concentration of 0.002 mg/L for which the*

MOE was unacceptable to children.

Suggested change:

"The modelled drinking water scenarios include drinking water intake where it is assumed:

- *a control on the level of lanthanum existed, for which the margin of exposure (MOE) was acceptable for both adults and children; and*
- *the lanthanum levels are well above the nominated controlled concentration and for which the MOE is lower than for the controlled concentration but nonetheless acceptable to adults and children."*

Reasons:

- The change reflects suggested alterations to the calculation of MOEs.
- The assumed water concentrations have been removed since they are in the preceding paragraph.
- See also rationale in Point [Request] 9 and where it states that the revision makes it clear the risk assessment scenarios and the water concentrations in them are illustrations for the purposes of assessing possible health effects in 'what if' type exposure scenarios.

Decision 1.10

Variation not approved.

NICNAS Response 1.10

The risks remain the same (see revised Table 9.2 in Response 1.87).

Request 1.11

Page ix, fourth paragraph

"These risk outcomes demonstrate that it is important to effectively manage the lanthanum levels in drinking water of the drinking water supply bodies treated with Phoslock™".

Suggested change:

"Notwithstanding these acceptable risk outcomes it is nonetheless important to effectively manage the lanthanum levels in drinking water sourced from supply bodies treated with Phoslock™."

Reasons:

- The change reflects the newly calculated MOEs.
- The change maintains the sensible precautionary advice to suppliers of drinking water.

Decision 1.11

Variation not approved.

NICNAS Response 1.11

This statement is relevant since the risks remain the same (see revised Table 9.2 in Response 1.87).

Request 1.12

Page ix, seventh paragraph

"The toxic effects associated with Phoslock™ are likely due to the dissolved lanthanum released to overlying water as the surface applied solutions settle through the water column to the sediment. However, the dissolved lanthanum analysed in the tests does not necessarily correspond to the ionic La^{3+} found in solution."

Suggested change:

"The toxic effects associated with Phoslock™ are likely due to the bioavailable lanthanum released to overlying water as the surface applied solutions settle through the water column to the sediment. However, the toxicity tests only measure filtered/dissolved lanthanum which does not necessarily correspond to the ionic or bioavailable La^{3+} found in solution."

Reason:

- Second paragraph in the 'Environmental effects' section already essentially equates bioavailable lanthanum with free or ionic lanthanum (La^{3+}). Therefore, substituting 'dissolved' for 'bioavailable' will carry this message forward and provide clarification throughout the document.

- The use of the term 'dissolved' interchangeably with 'bioavailable' is not appropriate, as it is well known that the filtered/dissolved concentration of metals are not necessarily a reflection of the concentrations of metal ions in solution responsible for aquatic toxicity (ANZECC 2000, pg. 7.4-2; Florence 1986; Bott 1996).

Decision 1.12

Variation partially approved.

NICNAS Response 1.12

Text to read as: "The toxic effects associated with Phoslock™ are likely due to the bioavailable lanthanum released to overlying water as the surface applied solutions settle through the water column to the sediment. However, the dissolved lanthanum analysed in the tests does not necessarily correspond to the ionic or bioavailable La^{3+} found in solution."

Request 1.13

Page x, second paragraph

"In fish sub-acute tests, the rainbow trout Oncorhynchus mykiss has a median effective concentration (EC50) of 200 mg/L Phoslock™ and a no-observed-effect-concentration (NOEC) of 40 mg/L Phoslock™ in softwater. The measured dissolved lanthanum levels at the LC50 and NOEC are 10-14 µg/L."

Suggested change:

"In one fish sub-acute test, the rainbow trout Oncorrhynchus mykiss had a median effective concentration (EC50) of 200 mg/L Phoslock™ and a no-observed-effect-concentration (NOEC) of 40 mg/L Phoslock™ in softwater. The measured dissolved lanthanum level at the EC50 and NOEC at the end of the test were 14 and 10 µg/L, respectively, but dissolved lanthanum levels at these test concentrations of Phoslock™ at any other point throughout the test are unknown. Authors of the study commented the data suggest either dissolved lanthanum is not primarily responsible for increased trout mortality or the dose response curve for dissolved lanthanum is very steep. Two other studies conducted with the same fish species showed lower sub-acute toxicity at 20 and >70 times higher Phoslock™ application rates (i.e. 4,350 mg/L and >13,600 mg/L Phoslock™), albeit dissolved lanthanum levels were not measured in these studies. The sub-acute toxicity of dissolved lanthanum from soluble lanthanum salts to other fish species seems to be much lower with 96-hour E(L)C50s ranging from >127 µg/L in rainbow fish (Stauber 2000) to 23,000 µg/L in zebrafish (RIVM 2000)."

Reason:

- The above shows that the results of the Clearwater and Hickey (2004) 96-hour rainbow trout study are not clear cut, and are somewhat at odds with toxicity information available for the same species from other studies, as well as for other species of fish.
- The above provides a more balanced summary of the ecotoxicity information available for fish, which affords an un-informed reader of the executive summary an appreciation of the variability and uncertainty of the fish results.

Decision 1.13

Variation partially approved

NICNAS Response 1.13

This section of the report aims to present the main critical findings, the specific details of which were discussed in the relevant sections of the report. To illustrate the authors' opinions on some of the studies, an additional paragraph will be added (see NICNAS Response to Request 1.15). Following on the corrections for the dissolved lanthanum levels for this particular study, the statement will be amended to read as:

"In fish sub-acute tests, the rainbow trout *Oncorhynchus mykiss* has a median effective concentration (EC50) of 200 mg/L Phoslock™ and a no-observed-effect-concentration (NOEC) of 40 mg/L Phoslock™ in softwater. The measured dissolved lanthanum level at the EC50 and NOEC at the end of the test were 14 and 10 µg/L, respectively, but dissolved lanthanum levels at these test concentrations of Phoslock™ at any other point throughout the test are unknown."

Request 1.14

Page x, third paragraph

"There is a wide range of test results for aquatic invertebrates. However, the effects of lanthanum chloride show a decreasing trend with increasing water hardness (filtered tap water to hard water) in acute toxicity tests to cladocerans. The lowest effect level for lanthanum toxicity to aquatic invertebrates was in Ceriodaphnia dubia with measured dissolved lanthanum of 20 µg/L at EC50 of >1 mg/L Phoslock™ in softwater."

Suggested change:

"There is a wide range of test results for aquatic invertebrates. However, the effects of lanthanum chloride show a decreasing trend with increasing water hardness (filtered tap water to hard water) in acute toxicity tests to cladocerans. The lowest chronic no effect concentration for dissolved lanthanum to aquatic invertebrates was from a study with Ceriodaphnia dubia, where no effects on survival or reproduction were observed even at the highest concentration of 1 mg/L Phoslock™ tested in softwater. Measured dissolved lanthanum was 20 µg/L."

Reason:

- Use of words "acute toxicity" in the first sentence may confuse the reader to thinking the second sentence is also referring to acute toxicity in *C. dubia*. The *C. dubia* 7-day reproduction/survival test is regarded as a chronic test (US EPA, 2007). It would be preferable to report the results of a chronic study as a No-Observed Effect Concentration rather than the EC50. Leaving the statements as they are could imply that immobilisation effects were observed in the test, but ESA (2008) report this is not the case.

Decision 1.14

Variation not approved.

NICNAS Response 1.14

ESA (2008) reported the result as "7-day EC50".

Request 1.15

Page x, fourth paragraph

"Chronic toxicity studies performed on sediment-dwelling organisms were done with sediments using natural lake/pond/spring water, with all tests conducted under hardwaters. The most sensitive species is the amphipod Phreatogammarus hemsii with observed chronic EC50 and NOEC of 33 and <20 mg/L Phoslock™, respectively, and 6-8 µg/L measured dissolved lanthanum."

Suggested change:

"Chronic toxicity studies performed on sediment-dwelling organisms were done with sediments using natural lake/pond/spring water, with all tests conducted under hardwaters. The most sensitive species is the amphipod Phreatogammarus helmsii with observed acute (i.e. 10-day) EC50 and NOEC of 33 and <20 mg/L Phoslock™, respectively, and 8 (or less) and 6 µg/L measured dissolved lanthanum at the end of the test. Authors of this study commented the mortality observed in the test may have been due to physical effects rather than direct toxicity of bioavailable lanthanum. In comparison, other acute, sub-chronic and chronic experiments with sediment-dwelling organisms have shown no toxicity with much higher doses of Phoslock™ (ranging from >400 mg/L to >3,400 mg/L). Where dissolved lanthanum was measured in overlying water in these tests, the concentration ranged from 7.7 to 483 µg/L with no toxicity observed."

Reason:

- The suggested changes provide a more balanced summary of the ecotoxicity information available for sediment-dwelling organisms, which affords an un-informed reader of the executive summary an appreciation of the variability and uncertainty of the results.

- The correct spelling of the amphipod species name, as per Clearwater and Hickey (2004) is *Phreatogammarus helmsii*.

Decision 1.15
Variation partially approved.

NICNAS Response 1.15
This section of the report aims to present the main critical findings, the specific details of which were discussed in the relevant sections of the report. However, NICNAS recognises that the authors' opinions on other contributing factors in the studies were not included in the summary. This paragraph will be amended and an additional paragraph will be included to read as:

"Chronic toxicity studies performed on sediment-dwelling organisms were done with sediments using natural lake/pond/spring water, with all tests conducted under hardwaters. The most sensitive species is the amphipod *Phreatogammarus helmsii* with observed acute EC50 and NOEC of 33 and <20 mg/L Phoslock™, respectively, and 6-8 µg/L measured dissolved lanthanum at the end of the test.

Although the studies aimed to determine the ecotoxicity effects of Phoslock™ or some soluble lanthanum salts, some of the authors suggested that the effects observed may be due to factors other than direct toxicity of dissolved lanthanum."

Request 1.16
Page x, fifth paragraph
"The amphipod P. hemsii study is used in deriving a revised predicted no effect concentration (PNEC) for ionic lanthanum based on the hierarchical framework of the Australian and New Zealand Guidelines for Fresh and Marine Water Quality and currently available lanthanum toxicity studies. A freshwater low reliability trigger value for ionic lanthanum is revised to 0.06 µg/L, which is comparable to a PNEC in this assessment."
Suggested change:
"Although there is uncertainty in whether or not the toxicity observed in the experiment conducted with P. helmsii was due to direct toxicity of bioavailable lanthanum, the dissolved lanthanum concentration of 6 µg/L in the overlying water dosed with 20 mg/L Phoslock™ is used in deriving a revised predicted no effect concentration (PNEC) for ionic (i.e. bioavailable) lanthanum based on the hierarchical framework of the Australian and New Zealand Guidelines for Fresh and Marine Water Quality and currently available lanthanum toxicity studies. A freshwater low reliability trigger (i.e. high uncertainty) value for ionic (i.e. bioavailable) lanthanum is revised to 0.06 µg/L, which is comparable to a PNEC for chronic exposure in this assessment. The equivalent low-reliability PNEC for acute exposure would be 0.6 µg/L for bioavailable lanthanum."
Reason:

- It is important to make it clear to the reader that there is considerable uncertainty involved in the PNEC. It is based on a very low concentration of dissolved lanthanum in a test which did not measure dissolved lanthanum at any other point than the very end of the experiment. The authors (Clearwater and Hickey 2004) comment on the incomprehensibility that a very small shift in dissolved lanthanum levels (of 2 µg/L) should cause an increase from 15% to 70% amphipod mortality. If the mortality was in fact due to physical effects of Phoslock™ rather than chemical toxicity *per se*, use of a dissolved lanthanum level to derive a PNEC is inappropriate.
- To an un-informed reader, the words 'low reliability trigger value' may not be explicit enough. Therefore it is suggested to include the words '(i.e. high uncertainty)' as well.
- It should be made clear that the derived PNEC is for chronic exposure, since an assessment factor of 100 was applied to the acute amphipod NOEC. The assessment factor of 100 includes: 1) a general uncertainty factor of 10 multiplied by 2) a default acute-to-chronic ratio of 10. The latter signifies that the derived PNEC is for chronic exposure.
- In the environmental risk assessment (see also rationale in Point [Request] 18), the PNEC for chronic exposure was directly compared to a peak (i.e. maximum) concentration of dissolved

lanthanum measured shortly after application. This is inappropriate. Many national and international guidance documents for risk assessment state that the characterisation of risk associated with chemical exposures should be done using a toxicity reference value (in this case the chronic PNEC) that is commensurate with the length of exposure (e.g. WHO 1999, US EPA 1989, ATSDR 2005, WHO 2010, enHealth 2012a). Therefore, it would be more appropriate to compare the chronic PNEC to a predicted environmental concentration 1-2 weeks after Phoslock™ application. An *acute* PNEC may be used for comparison to a peak (i.e. maximum) concentration, and this rationale has been carried forward in later points.

Decision 1.16

Variation partially approved

NICNAS Response 1.16

Refer to Decisions 1.78 and 1.83.

Text will be revised in overview to reflect the changes arising from Decision 1.78.

Request 1.17

Page x, eighth paragraph

"Significant release of dissolved lanthanum occurs 1-3 days after application of Phoslock™ granules in Australian and overseas environmental waters. The mechanisms underlying the much higher than expected release of dissolved lanthanum from Phoslock™ granules in environmental waters during this time are a function of the various water chemistry parameters as well as the equilibrium of ionic lanthanum binding with the available phosphorus."

Suggested change:

"The highest concentrations of dissolved lanthanum occur immediately after application of Phoslock™ granules, and have ranged from 10 to 220 µg/L in overseas and Australian environmental waters. It is unknown how much of the measured dissolved lanthanum is and remains bioavailable as ionic lanthanum. The mechanisms underlying the higher than expected concentrations of dissolved lanthanum after Phoslock™ application in environmental waters are a function of the various water chemistry parameters as well as the equilibrium of ionic lanthanum binding with the available phosphorus."

Reason:

- Use of word 'significant' is not defined, and there are several manners in which it could be interpreted. A more explicit wording is as suggested.
- Providing the range of measured dissolved lanthanum concentrations 0-3 days after application also gives the reader an appreciation of the variability in field applications.
- The second sentence reminds the reader of a statement made early on in the executive summary, that bioavailable (i.e. ionic) lanthanum may not necessarily be the same as dissolved lanthanum.

Decision 1.17

Variation approved.

NICNAS Response 1.17

Paragraph will be amended in the report.

Request 1.18

Page xi, second paragraph

"The peak dissolved lanthanum level is the critical parameter for which acute effects can be evaluated. The most appropriate predicted environmental concentration (PEC) determination is a peak level from actual field application results of the product. For the purposes of risk characterisation, the maximum peak dissolved lanthanum concentration of 220 µg/L is reasonably representative of the actual peak levels from Phoslock™ field applications and is taken as the PEC in this assessment."

Suggested change:

"The peak dissolved lanthanum level is the critical parameter for which acute effects can be evaluated. The most appropriate predicted environmental concentration (PEC) determination is a peak level from actual field application results of the product. For the purposes of risk characterisation, the maximum peak dissolved lanthanum concentration of 220 µg/L is reasonably representative of the worst case peak levels from an abnormal Phoslock™ field application and is taken as the PEC for acute exposure in this assessment."

Reasons:

- The word 'maximum' before 'peak' highlights the fact that this measured concentration is in fact the maximum measured in any of the samples taken.
- This maximum peak level should be considered a 'worst case' application, as recommended dosing was not adhered to, and maximum dissolved lanthanum concentrations on the day of application in other field studies have ranged from 10-110 µg/L. In addition, it is highly unlikely the maximum concentration measured would be uniformly distributed in a water body.
- The PNEC for acute effects should be compared to the maximum PEC of dissolved lanthanum used in the assessment. Field applications have shown the concentrations of dissolved lanthanum decrease considerably within one week of Phoslock™ application. Thus it is inappropriate to use the maximum peak dissolved lanthanum concentration for direct comparison to the chronic PNEC. Instead either 1) the maximum peak concentration is used as the sole PEC, the PNEC should be adjusted to a PNEC for acute exposure (i.e. by not applying the default acute-to-chronic ratio of 10), or 2) two PECs and two PNECs should be derived, one for acute and the other for chronic exposure.
- If a PNEC for chronic effects is used in the risk assessment, the PEC should also be reflective of a chronic exposure concentration. Suggested variations could be: "*The worst case PEC for chronic exposure would be a concentration of dissolved lanthanum 1-2 weeks after Phoslock™ application. The average of maximum dissolved lanthanum concentrations one week after various field applications was approximately 50 µg/L, which can be considered a PEC for chronic exposure*." (Refer to revised Table 5.1 see Appendix [shown in Request 1.40])

Decision 1.18

Variation partially approved.

NICNAS Response 1.18

Paragraph to be amended as: "The peak dissolved lanthanum level is the critical parameter for which acute effects can be evaluated. The most appropriate predicted environmental concentration (PEC) determination is a peak level from actual field application results of the product. For the purposes of risk characterisation, the maximum peak dissolved lanthanum concentration of 220 µg/L is reasonably representative of the worst case peak levels achievable under any conditions of Phoslock™ field application and is taken as the PEC for acute exposure in this assessment."

Request 1.19

Page xi, third and fourth paragraphs

"The environmental risks associated with the use of Phoslock™ to prevent nuisance algal blooms in environmental water bodies include a high risk of adverse effects on aquatic organisms in some application scenarios. In these scenarios, the risk quotient (RQ) for Phoslock™ in the water column is significantly greater than one, based on the dissolved lanthanum level that peaks 1-3 days after application and a conservative low reliability PNEC derived from laboratory toxicity data.

The environmental risks of Phoslock™ are essentially the environmental risks of the dissolved or ionic lanthanum it contains, and the environmental speciation, fate and toxicity of lanthanum are strongly dependent on water chemistry. The available data suggest that the environmental risks are highly site-specific. The RQ approach is based on highly conservative PEC and PNEC values derived under worst case water chemistry conditions. There are difficulties in relating risks based on laboratory toxicity data with the risk to Phoslock™ in the aquatic field environment, particularly due to differences in the form of lanthanum related to variations in water chemistry and the considerable uncertainty on factors affecting toxicity to aquatic organisms. The refinement of risk characterisations is essential where suitable models and data are available."

Suggested change:

"The environmental risks associated with the use of Phoslock™ to prevent nuisance algal blooms in environmental water bodies include a possible risk of adverse effects on sensitive aquatic organisms in some application scenarios. In these scenarios, the risk quotient (RQ) for Phoslock™ in the water column is significantly greater than one, based on the dissolved lanthanum level that peaks on the day of application and a conservative low reliability PNEC derived from laboratory toxicity data. It is noted there is high uncertainty associated with the study from which the PNEC was derived.

The environmental risks of Phoslock™ are most probably due to the environmental risks of the bioavailable (i.e. ionic) lanthanum it contains, and the environmental speciation, fate and toxicity of lanthanum are strongly dependent on water chemistry. The available data suggest that the environmental risks are highly site-specific. The RQ approach is based on highly conservative PEC and PNEC values derived under worst case water chemistry conditions. There are difficulties in relating risks based on laboratory toxicity data with the risk to Phoslock™ in the aquatic field environment, particularly due to differences in the form of lanthanum related to variations in water chemistry and the considerable uncertainty on factors affecting toxicity to aquatic organisms. The refinement of risk characterisations is essential where suitable models and data are available."

Reason:

- The additional sentence at the end of the first paragraph again reminds the reader of the level of uncertainty involved with the derived PNEC, due to the uncertainty of the study from which it was derived. This has already been discussed elsewhere (see Points [Requests] 15 and 16).
- The changes to the first sentence of the next paragraph reiterate that environmental risks from Phoslock™ are most probably due to the bioavailable, not necessarily the dissolved, lanthanum it contains. There is still uncertainty in laboratory toxicity studies of whether or not it is the bioavailable lanthanum that is causing any observed ecotoxicity or some other artefact (e.g. physical effects at high doses of Phoslock™) (e.g. Clearwater and Hickey 2004).

Decision 1.19

Variation partially approved.

NICNAS Response 1.19

The uncertainties associated with the PNEC are sufficiently described elsewhere and emphasised by referring to a "conservative low reliability PNEC". The word "dissolved" will be replaced by "ionic".

Request 1.20

Page xii, first paragraph

"Site-specific direct toxicity testing is currently necessary for Phoslock™ considering the current uncertainties on the environmental fate and toxicity of the chemical and the toxic ionic lanthanum component possibly released in aquatic ecosystems."

Suggested change:

"Site-specific direct toxicity testing is recommended for Phoslock™ considering the current uncertainties on the environmental fate and toxicity of the chemical and the toxic ionic lanthanum component possibly released in aquatic ecosystems."

Reason:

- The original sentence is ambiguous as to whether or not site-specific direct toxicity testing is already being performed in considering a Phoslock™ application to a water body. The suggested change clarifies what we believe is meant by NICNAS, i.e. that direct toxicity testing is recommended.

Decision 1.20

Variation approved.

NICNAS Response 1.20

Amended text will be incorporated in the report.

Request 1.21

Page xii, second dot point

"2. *In hardwater or high alkalinity water (>60 mg/L CaCO3), reduced toxicity has generally been observed, with the exception of some midge and/or amphipod wherein minimal sublethal effects occurred at dissolved lanthanum concentrations <10 µg/L."*

Suggested change:

"2. *In hardwater or high alkalinity water (>60 mg/L CaCO3), reduced toxicity has generally been observed, with the exception of a single amphipod study wherein minimal sublethal effects occurred at dissolved lanthanum concentrations <10 µg/L. However there is considerable uncertainty in whether the effects observed can be attributed to dissolved lanthanum."*

Reason:

- Toxicity to the amphipod *P. helmsii* was observed in a single study (Clearwater and Hickey 2004). Other acute, sub-chronic and chronic ecotoxicity studies conducted with sediment dwelling organisms, which included both midge larvae and a different species of amphipod (*Hyalella azteca*)[1], have shown no toxicity with much higher doses of Phoslock™ than applied in the Clearwater and Hickey (2004) experiment with *P. helmsii* (i.e. 400 mg/L to >3,400 mg/L) (Watson-Leung 2009, Clearwater 2004, Clearwater and Hickey 2004). Where dissolved lanthanum was measured in overlying water in these tests, the concentration ranged from 7.7 to 483 µg/L with no toxicity observed (Clearwater and Hickey 2004, Clearwater 2004).
- The reference to uncertainty observed in the study relates to the unlikelihood that a very slight increase in dissolved lanthanum in overlying water (from 6 to 8 µg/L) could account for a vast difference in the toxicity observed (15% vs. 70% mortality). The authors of the paper hypothesised something other than the toxicity of bioavailable lanthanum *per se* may be responsible for the effects observed (e.g. physical effects of Phoslock™ at high doses).

[1] Note this species of amphipod is commonly used in regulatory toxicity testing.

Decision 1.21

Variation approved.

NICNAS Response 1.21

Additional sentence will be incorporated in the report.

Request 1.22

Page xiii, Framework for the management of risks to Phoslock™ application, Risk framework table, under 'Lower risk potential'

"The key water chemistry parameters (pH, hardness/alkalinity, total phosphorus and FRP, total and dissolved lanthanum, DO/DOC, chlorophyll-a) are to be measured in all stages of the pre- and post-application monitoring, with indicative DTA requirements presented in Table 11.4."

Suggested change:

It is suggested the phrase *", with indicative DTA requirements presented in Table 11.4 be deleted."*

Reason:

- During a meeting with PWS and NICNAS (January 9th 2013), there was the acknowledgement by NICNAS attendees that the DTA's are recommendations and are not required to be undertaken by all or any of the States and Territories if not deemed necessary.
- NICNAS have acknowledged (page 96 of the Draft report) that "Phoslock™ can be applied in hard waters regardless of the FRP level….". This suggests that there is no need for direct toxicity testing in hard waters.

Decision 1.22

Variation not approved.

NICNAS Response 1.22

The NICNAS findings in Section 11.3.3 (page 96, first paragraph of the subsection) stated the optimal conditions for which Phoslock™ can be applied. This does not imply that the DTA testing would not be needed. Note that the approved suggestion in Request 1.20

clarifies that this is clearly a recommendation.

Request 1.23

Section 1.1, Page 1, second paragraph

"No toxicological studies were available for the chemical".

Suggested change:

"No toxicological studies were available for the formulated product".

Reason:

- Phoslock is not a chemical, rather a combination of substances.

Decision 1.23

Variation not approved.

NICNAS Response 1.23

Phoslock™ is a reaction product of bentonite clay and lanthanum chloride. A reaction product is a combination of substances and is considered a chemical. In the current case, the lanthanum is incorporated into the bentonite, rather than simply being a mixture.

Request 1.24

Section 1.1, Page 1, fifth paragraph

""The aquatic hazard is principally related to the potential release of lanthanum ions from this chemical, which are very toxic to freshwater invertebrates in soft water".

Suggested change:

""The aquatic hazard is principally related to the potential release of lanthanum ions from this formulated product, which are potentially toxic to freshwater invertebrates in soft water".

Reason:

- Phoslock is not a chemical, rather a combination of substances (as in Point [Request] 23 above).
- Work undertaken at ESA, 2008 showed that lanthanum ions associated with Phoslock did not show any toxicity to *Ceriodaphnia dubia* in soft water (with average total alkalinity 15.5 mg/L in experimental water). Average total alkalinity at Deep Creek was 28 mg/L, almost double the measured laboratory total alkalinity.

Decision 1.24

Variation not approved.

NICNAS Response 1.24

Phoslock™ is a reaction product of bentonite clay and lanthanum chloride. A reaction product is a combination of substances and is considered a chemical. However, the word "very" will be removed.

Request 1.25

Section 1.1, Page 2, second paragraph

"... a number of dead small fish were found floating in the reservoir and fish apparently continued to die for up to two weeks after application of the chemical"

Suggested change:

"... a small number of fingerlings were found floating in the reservoir and fish apparently continued to die for up to two weeks after application of the product and soda ash. However the death of fingerlings was observational and no scientific study was undertaken during this time."

Reasons:

- Phoslock is not a chemical, rather a combination of substances (as in Point [Request] 23 above).

- Inclusion of 'soda ash' provides a better description of how Deep Creek water was treated.
- Clarification of the age and small number of fish found dead by the reservoir manager.
- References used in the report to provide evidence of the fish deaths are letters and an email and are not evidence presented in a scientific report (NSW DECC, 2007a & b; 2008a).

Decision 1.25
Variation not approved.

NICNAS Response 1.25
Ecotoxicity testing (including fish) and lanthanum level determination were conducted by the then NSW DECC and provided to NICNAS.

Request 1.26
Section 1.1, Page 2, third paragraph
"A number of additional laboratory ecotoxicity studies of formulated products containing Phoslock™"
Suggested change:
"A number of additional laboratory ecotoxicity studies have been conducted with the formulated Phoslock product."
Reason:

- The existing sentence implies other products are made from, or contain Phoslock. This is incorrect.

Decision 1.26
Variation approved.

NICNAS Response 1.26
Text will be amended in the report.

Request 1.27
Section 1.1, Page 2, fourth paragraph
"Additionally, it is now intended that Phoslock™ be marketed for the treatment of drinking water reservoirs."
Suggested change:

- Delete this sentence

Reason:

- There is no intention by Phoslock Water Solutions to directly market Phoslock for the treatment of Australian drinking water reservoirs.

Decision 1.27
Variation not approved.

NICNAS Response 1.27
This information has been provided to NICNAS in the application for secondary notification assessment. However, the whole statement will not be deleted but will be rephrased to read as: "Additionally, Phoslock™ may also be used for the treatment of drinking water reservoirs".

Request 1.28

Section 1.4, Page 3, first paragraph

"The product has been used to reduce cyanobacterial blooms in the recreational waters of the Clatto Reservoir and Loch Flemington in Scotland with the Scottish Environmental Agency (SEPA) having undertaken water quality testing before and after product application."

Suggested change:

"The product has been used to reduce cyanobacterial blooms in the recreational waters of the Clatto Reservoir and Loch Flemington in Scotland with the Scottish Environmental Agency (SEPA) and the Centre for Ecology and Hydrology (CEH) having undertaken water quality testing before and after product application."

Reason:

- There were two departments working on the above mentioned water bodies. Both departments have published work from the applications and the reader would benefit from this knowledge.

Decision 1.28

Variation approved.

NICNAS Response 1.28

Additional information will be added in the report.

Request 1.29

Section 1.4, Page 4, fifth paragraph

Suggested addition:

"Phoslock™ has been tested and granted NSF ANSI 60 certification for application to drinking water in North America (Phoslock Phosphate Sequestering Agent, certificate # Revision: 01/07/2013, reference WQA Web Portal, http://12.2.248.199/goldseal/detail2.cfm?tableDefID=6&companyID=6506).

Reason:

- Added information for the reader.

Decision 1.29

Variation approved.

NICNAS Response 1.29

Additional information will be included.

Request 1.30

Section 2.2, Page 5, second paragraph

"The physical properties of Phoslock™ manufactured in China have not been reported. It is therefore not known whether the new manufacturing process has significantly changed key physical properties of this clay-based chemical including the size of its fundamental clay particles, their cation exchange capacity (CEC), and the settling velocities of the particles in water. The only physical properties available are for the granulated end-use product, which prior to 2007 contained >90% Phoslock™ combined with up to 5% precipitated silica dispersing agent. "

Suggested change delete above and replace with:

"The changes and improvements to the manufacture of Phoslock™ have been submitted in the form of a process flow chart, product label and MSDS and the physical properties of the product remain consistent, as previously documented, for the granulated end–use product. Additional manufacturing steps introduced at the commencement of commercial production, which include dewatering and granulation of the original patented slurry formula, greatly reduce the amount of unbound lanthanum ions within the Phoslock™ clay matrix and improve the handling characteristics. Prior to 2007, Phoslock™ contained up to 5% precipitated silica dispersing agent.

Reason:

- To the best of our knowledge, PWS has provided this information to NICNAS in the form of the MSDS, PWS reports and other communication.

- It is not clear to the reader what *“>90%Phoslock™”* refers to.
- The additional steps should be considered process improvements to the original patented slurry and not a “new manufacturing” process.”

Decision 1.30

Variation partially approved.

NICNAS Response 1.30

PWS reports and MSDS have been previously provided, noting that the MSDS does not provide any process modifications of the product. The “>90% Phoslock™” refers to the lanthanum modified clay chemical (Bentonite, lanthanian with CAS No. 302346-65-2) content in the granular Phoslock™ product as stated in PWS documents (i.e. PWS, 2006; Groves, 2010), which were cited in the report. Since the original formulation of the product was a slurry with 10–30% Phoslock™, the process improvement of producing a granular form of the product containing >90% Phoslock™ is considered a new manufacturing process. The paragraph will be modified to read as:

“The physical properties of Phoslock™ manufactured in China have not been reported. It is therefore not known whether further manufacturing steps involved in the production of the granular product (e.g. dewatering and granulation of the original slurry formulation) has significantly changed key physical properties of this clay-based chemical including the size of its fundamental clay particles, their cation exchange capacity (CEC), and the settling velocities of the particles in water. The additional manufacturing steps could reduce the amount of unbound lanthanum ions within the Phoslock™ clay matrix and improve the handling characteristics). The granular form is now composed of >90% lanthanum modified clay. Prior to 2007, the product contained up to 5% precipitated silica dispersing agent.”

Request 1.31

Section 2.2, Page 6, Table 2.1

“Dispersing agent Precipitated silica (2.5-5%)”

Suggested change:

Delete “Dispersing agent Precipitated silica (2.5-5%)” from table

Reason:

- There is no silica dispersing agent in Phoslock.
- This has been removed in the draft report in other places; however this entry in the table has been overlooked.

Decision 1.31

Variation not approved.

NICNAS Response 1.31

The second paragraph after Table 2.1 indicated that precipitated silica has ceased to be added in formulations post 2007. The statement is retained to reflect the change in formulation of the product.

Request 1.32

Section 2.3.3, Page 8, second paragraph

“The mechanisms underlying efficient release of lanthanum ions from Phoslock™ granules in environmental waters are currently not known.”

Suggested change:
"The mechanisms underlying the release of lanthanum ions from Phoslock™ granules in environmental waters are currently not known."
Reason:
- It is not intended lanthanum ions be released so 'efficient' is inappropriate.

Decision 1.32
Variation approved.

NICNAS Response 1.32
Word 'efficient' will be removed from the sentence.

Request 1.33
Section 2.4, Page 8, first paragraph
"The routine methods of analysis for Phoslock™ granules have not been provided."
Suggested change:
"The routine methods of analysis for Phoslock™ granules are elemental analysis, lanthanum leach testing, FRP removal, pH of hydrated slurry, moisture content and particle sizing."
Reason:
- Phoslock Water Solutions believes that this Information on the routine methods of analysis (QA/QC) for Phoslock granules has been provided to NICNAS however this may have been overlooked. A list of these documents can be found in the PWS Reference Documents section: 1(a-f) at the end of this report and are also available to NICNAS upon request.

Decision 1.33
Variation approved.

NICNAS Response 1.33
The following sentence which refers to the likely test methods will be removed given this information more accurately addresses this issue.

Request 1.34
Section 2.4, Page 8, last paragraph
"... to which it is applied.
Suggested change, add the following:
"... to which it is applied. Of the various chemical species of lanthanum present, lanthanum ions are expected to be the most readily bioavailable, on the other hand highly insoluble species such as lanthanum phosphate will have very poor bioavailability (see Section 8).
Reason:
- The addition provides contextual information for the reader.

Decision 1.34
Variation partially approved.

NICNAS Response 1.34
Sentence will be added but slightly modified to read as: "... to which it is applied. Unbound lanthanum ions are expected to be readily bioavailable compared to insoluble lanthanum species (e.g. lanthanum phosphate) (refer to Section 8)".

Request 1.35

Section 3.2, Page 9, first paragraph and Table 3.1

"Recent information from the company indicated import volumes for the 2010/11 with no further imports anticipated at this time."

Suggested change:

"Recent information from the company indicated import volumes for 2010/11 and 2011/12."

Reason:

- Phoslock Water Solutions believes that this Information on import volumes has been provided however may have been overlooked. Imports for 2011/12 for granules were 42 metric tonnes and there were no Powder imports.

Decision 1.35

Variation approved, noting that NICNAS has no record of this information being provided prior to the publication of the draft report.

NICNAS Response 1.35

The sentence will be amended to reflect the recently received information.

Request 1.36

Section 3.3, Page 9, first paragraph

"... to be used to control soluble phosphate concentrations..."

Suggested change:

"... to be used to control concentrations of filterable reactive phosphorous..."

Reason:

- The change is more technically correct.

Decision 1.36

Variation not approved.

NICNAS Response 1.36

The statement is clearly identified as a direct quote from the original Phoslock™ assessment NA/899 in 2001.

Request 1.37

Section 3.3, Page 9, second paragraph

"Data provided for this secondary notification states that the applicant's market focus had shifted more towards treatment of larger water bodies with an intention to treat an estimated two major drinking water and/or recreational reservoirs in every Australian state or territory."

Delete this sentence:

Reason:

- The extent of market focus for treating drinking water reservoirs depends on market forces and environmental conditions and is not considered a Phoslock Water Solutions marketing priority for Australia.

Decision 1.37

Variation not approved.

NICNAS Response 1.37

This information was provided to NICNAS in the Secondary Notification application in 2007. Reference to market focus will be deleted in consideration of the current priority of the company. Statement to read as:

“Information provided for this secondary notification states that the applicant expects to apply the product in larger water bodies which may include treatment of an estimated two major drinking water and/or recreational reservoirs in every Australian state or territory.”

Request 1.38

Section 5.2.1, Page 13, second paragraph

“... the latter are not expected to persist in the water body. On this basis, primary exposure scenarios will consider soluble lanthanum.”

Suggested change:

“... the latter are not expected to persist in the water body and be readily bioavailable. On this basis, primary exposure scenarios will consider soluble lanthanum, i.e. lanthanum ions.”

Reasons:

- The change provides additional rationale and clarity why the assessment focus, as stated, is on soluble lanthanum and what this is.
- The change is consistent with considerations in Section 5.2.2.

Decision 1.38

Variation approved.

NICNAS Response 1.38

Text will be amended in the report.

Request 1.39

Section 5.2.1, Page 14, second paragraph

“... at the time of application has not been resolved.”

Suggested change:

“... at the time of application has not been resolved (see Section 6.2.5 for discussion).

Reason:

- The change provides appropriate cross referencing for the reader.

Decision 1.39

Variation approved.

NICNAS Response 1.39

Additional text to be reflected in the report.

Request 1.40

Section 5.2.1, Page 14, second and third paragraphs and Table 5.1

“For example, water samples taken ... may occur upon changes to water conditions. Measurement of lanthanum in monitored water bodies...”

Suggested change:

Delete the nominated text and replace with.

“Table 5.1 summarises measurements of dissolved lanthanum at various times after treatment in a number of applications of Phoslock to water bodies. Immediately, or soon after application, dissolved lanthanum was at an average of 94 µg/L (range 10 – 220 µg/L, n = 8). After 8 weeks the average concentration was 12 µg/L (range <2 – 40 µg/L, n = 11). It is noted sampling sites and depth, and rain events after application may have influenced the measurements. Overall measurement of lanthanum in monitored water bodies...”

Delete Table 5.1 and replace with:

Table 5.1:

		Measured maximum soluble lanthanum concentration post-application (µg/L)			
Treatment site	**Date**	**Day 0**	**1 week**	**4 weeks**	**8 weeks**
Australian Sites					
Torrens Lake, Australia	6-8/3/07	110	5	24	5
Deep Creek Reservoir, Australia	2-5/4/07	220*	ND	98	33
Gnowangerup Dam No. 2, Australia	30/01/2008	10	<5	ND	ND
University of Queensland, Australia	1/08/2006	60	30	10	<10
Overseas Sites					
Silbersee, Germany	14-15/11/2006	110**	60	30	40
Otterstedter See, Germany	30 Oct-1/11/2006	90	80	ND	10
Barensee, Germany	12-13/6/2007	ND	90	20	<10
Rauwbraken, Netherlands	21/04/2008	ND	ND	41^	4
De Kuil, Netherlands	18-21/5/2009	ND	ND	2	<2
Lake Niedersachsen, Netherlands	19/03/2008	100	91^^	14^	5
Sentosa, Singapore	1/11/2006	ND	97	ND	22***
Mill Pond, USA	22/08/2011	52	26	18	<10
Average		94	53.5	28.5	12
number (n)		8	9	9	11
Range		10-220	<5-97	2-98	<2-40
* - Measured at 3 days post-application;					
**Measured 4 days post -application					
***Measured 7 weeks post-application					
^ Measured 3 weeks post-application					
^^ Measured 2 weeks post-application					
ND - Not Determined					
Values in red - NICNAS data but PWS unsure where the data has been sourced					

Reasons:

- The change is consistent with the general overview provided by Section 5.2.1 and provides the reader with a broader and more accurate view of the levels of soluble lanthanum that have been measured.
- Detailed descriptions of the trials in Table 5.1 are provided in Sections 6.2.5 and 6.2.6 of the NICNAS report and are not required here.
- The additional text and information in Table 5.1 supports the contention being made in the fore going paragraph (starting with "*As discussed in Section 5....*") that the amount of dissolved lanthanum is variable. This is not as discernible when only three applications are summarised in the existing Table 5.2.

Decision 1.40

Variation not approved.

NICNAS Response 1.40

Note that additional data (Sentosa, Mill Pond, Lake Niedersachsen, Otterstedter See) have been included in the Table by PWS. The lanthanum levels indicated in the table do not match with the values as discussed in Section 6.2.6. In determining the lanthanum levels to be used for the estimation of public exposure, data are preferred reflecting the Australian conditions. Furthermore, to include the overseas studies and consider using the average values across all monitored sites would contribute to greater uncertainty in exposure assessment, and consequently in the risk assessment.

Request 1.41

Section 5.2.1, Page 14, last paragraph

"... a controlled concentration of lanthanum in drinking water to examine..."

Suggested change:

"... a controlled concentration of lanthanum in drinking water (i.e. tap water) to examine...."

Reason:

- The change clarifies what is meant by drinking water and is consistent with the assessment scope as described in Section 5.2.

Decision 1.41

Variation partially approved.

NICNAS Response 1.41

Statement to read as: "... a controlled concentration of lanthanum in drinking water as provided to the consumer to examine...."

Request 1.42

Section 5.2.1, Page 15, second paragraph

"... treat both drinking water and ..."

Suggested change:

"... treat both water that may be a source for drinking water and ..."

Reason:

- The change improves the accuracy of the statement since Phoslock is not used to produce drinking water.

Decision 1.42

Variation approved.

NICNAS Response 1.42

Change will be reflected in the report.

Request 1.43

Section 5.2.2, Page 15, first paragraph

"Individuals may be exposed to lanthanum in water when consuming water directly as a beverage, indirectly from food and drinks containing water, or incidentally while swimming. However, these forms of exposure are likely to be relevant only for the limited populations consuming water from, or swimming in, treated water bodies. It is unlikely that individuals will be exposed from both sources.

Suggested change:

"Individuals may be exposed to lanthanum in drinking water when consuming tap water as a beverage, indirectly from food and drinks containing water, or directly from swallowing the treated water or incidentally while swimming. However, the latter forms of exposure are likely to be relevant only for the limited populations consuming water directly from, or swimming in, the treated water bodies. It is unlikely that individuals will be exposed via both routes of exposure. As discussed in Section 9.4 most polishing treatments used to prepare drinking water will dramatically reduce the concentrations of lanthanum from the source water.

Reason:

- The change improves the clarity and meaning of the paragraph.
- Since it is not known for certain that the public will be exposed to lanthanum in drinking water (i.e. tap water), the word 'potentially' has been added to make the uncertainty clearer.
- The change also provides cross reference to the discussion provided in Section 9.4 at an appropriately early point in the assessment.

Decision 1.43

Variation partially approved.

NICNAS Response 1.43

The paragraph will be amended to read as: "Individuals may be exposed to lanthanum in drinking water when consuming tap water as a beverage, indirectly from food and drinks containing water, or directly from swallowing the treated water or incidentally while swimming. However, the latter forms of exposure are likely to be relevant only for the limited populations swimming in the treated water bodies. It is rare that individuals will be exposed via both routes of exposure. As discussed in Section 9.4 the treatments used to prepare drinking water from the source water are expected to reduce the concentrations of lanthanum compared with the source water."

Request 1.44

Section 5.2.2, Page 15, third paragraph

"...; in its absence, 100% uptake is assumed..."

Suggested change:

"...; in its absence, a conservative estimate, up to 100% uptake is assumed...."

Reason:

- The suggested change reflects the fact that not in all risk assessments, in the absence of specific data, is it automatically assumed 100% of the oral dose is absorbed.

Decision 1.44

Variation partially approved.

NICNAS Response 1.44

Statement will read as: "...; in its absence, a conservative estimate of 100% uptake is assumed."

Request 1.45

Section 5.2.2, Page 15, 4th paragraph

"... bioavailability of soluble lanthanum is much higher than for the carbonate. As there is insufficient specific information available, an uptake of 100% for soluble lanthanum is assumed".

Suggested change:

"... bioavailability of lanthanum from soluble salts is potentially higher than from the carbonate. This is evinced by the bioavailability from the insoluble carbonate being <0.002% and that from soluble lanthanide nitrates about 0.066% (Section 7.1.1). Although there is a lack of specific information on the bioavailability of soluble lanthanum ions the available data suggests they are unlikely to be 100% absorbed. Lanthanum carbonate solubilises in stomach acid, dissociating into lanthanum ion and carbonate (Section 7). The bioavailability data for lanthanum carbonate in healthy volunteers indicates poor bioavailability of the dissociated lanthanum ions during passage through the intestines (Pennick et al. 2006). The same will apply to lanthanum ions derived from soluble lanthanum salts or Phoslock. This is probably due to tight binding of the dissociated ions to constituents of the gastrointestinal contents. For example lanthanum binds with high affinity to dietary phosphate, the resulting salt is excreted in faeces; this is the mode of action governing the use of lanthanum carbonate as a therapeutic agent (Curran and Robinson 2009). In the acid environment the dissociated carbonate easily decomposes to carbon dioxide and water (Lewis 2006) and hence is unlikely to recombine with lanthanum ions in the intestine. In recognition of the uncertainty regarding the absorption of lanthanum ions from the gastrointestinal tract it is conservatively assumed the bioavailability of soluble lanthanum in water is 10%. This is more than two orders of magnitude higher than what is reported for the soluble lanthanide nitrates and accounts for the deficiencies in the study noted in Section 7.1.1.and lack of specific data for lanthanum ions."

Reason:

- There is a large excess (~16,000 fold) of dietary phosphate intake compared with the assumed worst case intake of soluble lanthanum from the risk assessment. The intake for the worst case scenario is 0.03 mg/L x 2L/d = 0.06 mg/d, whereas intake of dietary phosphate is ~1,000 mg/d (http//emedicine.medscape.com/article/242280-overview). The large excess of phosphate ensures the concentration of 'free' absorbable lanthanum ion in the gastrointestinal tract is very low. As a consequence the bioavailability of soluble lanthanum in drinking water will be very low, certainly a lot less than the assumed 100%.

- It is patently unrealistic to assume 100% of ingested soluble lanthanum is absorbed.
- The rationale for 10% bioavailability, 150 times higher than for the lanthanide nitrates, provides an appropriate precautionary margin in light of the limited data available for absorption of La3+ from the gastrointestinal tract.
- The 10% bioavailability of lanthanum chloride is 5,000 times higher than the bioavailability of Lanthanum from lanthanum carbonate.

Decision 1.45
Variation partially approved.

NICNAS Response 1.45
The calculation of systemic or internal oral exposures will not be considered since the critical NOAELs taken forward in the risk estimation were all external doses. Thus, the discussion on oral bioavailability is not relevant in this section. The following will be deleted in Section 5.2.2:

- Fifth paragraph on page 15;
- Fourth dot point on page 15;
- B_{oral} / 100 in Equation 1 of page 15

In addition, any reference to 'internal oral exposure' or 'internal dose' will be replaced with 'received oral exposure' or 'received dose'. PWS has provided useful information in the suggested change and some of this information will be utilised in Section 7.1.1. I_{oral} will now be amended to be D_{oral}.

Request 1.46
Section 5.2.2, Page 15, 6th paragraph, 4th dot point
"Lanthanum bioavailability via the oral route is 100%."
Suggested change:
"Lanthanum ion bioavailability via the oral route is 10%".
Reason:
See rationale in Point [Request] 1.45 above.

Decision 1.46
Variation not approved.

NICNAS Response 1.46
Refer to Response 1.45.

Request 1.47
Section 5.2.2, Page 16, Table 5.2

"**Table 5.2.Calculated daily internal doses from oral exposure to direct ingestion of drinking water containing soluble lanthanum.**

	I_{oral} (µg/kg bw/day)	
	Controlled	**Reasonable worst-case**
Child	0.2	3.3
Adult	0.06	0.94

Suggested change:

Table 5.2.Calculated daily internal doses from oral exposure to ~~direct~~ ingestion of ~~drinking~~ water containing soluble lanthanum.

	I_{oral} (µg/kg bw/day)	
	Controlled	**Reasonable worst-case**
Child	0.02	0.33
Adult	0.006	0.094

Reasons:

- The changes in Table 5.2 are a cascade of the suggested change in Request 45 above.
- The deletion of 'drinking' in the title to Table 5.2 is to remove ambiguity that the lanthanum doses relate to tap water. Since the concentrations (2 & 33 µg/L) used to derive the doses for each scenario are for source water, the resulting intake doses are also for ingestion of source water and not drinking (tap) water.

Decision 1.47

Variation not approved.

NICNAS Response 1.47

The table will reflect received dose instead of internal dose. The bioavailability component should not affect the numbers in the table since 100% bioavailability was used in the original calculation. Reference to I_{oral} will be amended to D_{oral}.

Table 5.2. Calculated daily internal doses from oral exposure to direct ingestion of drinking water containing soluble lanthanum.

	D_{oral} (µg/kg bw/day)	
	Controlled	**Reasonable worst-case**
Child	0.2	3.3
Adult	0.06	0.94

Request 1.48

Section 5.2.2, Page 16, last sentence (immediately under Table 5.2)

"The ingested amounts to which the majority of people will be exposed will be highly variable and lower than these worst case estimates."

Suggested change:

"The ingested amounts to which the majority of people will be exposed will be variable ,and lower than these worst case estimates because polishing treatments of source water will remove most, if not all lanthanum ions (Section 9.4)."

Reason:

The suggested change clarifies how the majority of people will be exposed.

Decision 1.48

Variation partially approved.

NICNAS Response 1.48

Statement slightly modified to read as: "The ingested amounts to which the majority of people will be exposed will be variable and possibly lower than these worst case estimates because water treatment processes used to prepare water as supplied to the consumer are expected to remove a proportion of the lanthanum ions (Section 9.4)."

Request 1.49

Section 6.2.2, pg. 20, first paragraph

"The bioavailability of lanthanum from Phoslock™ is principally due to the presence of the free or dissolved lanthanum ions La^{3+} which are available for uptake by aquatic organisms."

Suggested change:

"The bioavailability of lanthanum from Phoslock™ is principally due to the presence of the free lanthanum ions La^{3+} which are available for uptake by aquatic organisms."

Reason:

- The use of the term 'dissolved' interchangeably with 'bioavailable' is not appropriate, as it is well known that the filtered/dissolved concentration of metals are not necessarily a reflection of the concentrations of metal ions in solution responsible for aquatic toxicity (ANZECC 2000, pg. 7.4-2; Florence 1986; Bott 1996).

Decision 1.49

Variation approved.

NICNAS Response 1.49

Text will be amended accordingly.

Request 1.50

Section 6.2.5, page 30, last sentence

"A biological survey of water samples taken from the reservoir about 7 weeks after application also found almost no living zooplankton, considered to be unusual for this type of water body (NSW DECC, 2007b)."

Suggested change:

"A biological survey of water samples taken from the reservoir about 7 weeks after application also found almost no living zooplankton, considered to be unusual for this type of water body (NSW DECC, 2007b), although pre-application monitoring was not carried out and a reduction in numbers of zooplankton could have also been temporary due to a reduction in their food source."

Reason:

- Laboratory experiments have shown that precipitation of lanthanum and phosphorus (presumably as insoluble LaPO4) occurs in test vessels when lanthanum is dosed into a P-containing medium (Lurling and Tolman 2010, Stauber and Binet 2000). Lurling and Tolman (2010) confirmed that the removal of phosphorus from the test medium limits the food source for the aquatic invertebrates tested, thereby causing the apparent toxicity observed.
- In a field situation, an ecosystem is expected to be able to recover from food limitation. This is not considered to be a direct adverse effect of Phoslock™, as the purpose of Phoslock™ is to limit nutrients for algal species to reduce algal blooms. According to Lurling and Tolman (2010), despite possible short-term reduction in juvenile invertebrate survival and growth such minor effects will be outweighed by significant reductions in the amount of cyanobacteria in the water body.

Decision 1.50

Variation partially approved.

NICNAS Response 1.50

Statement to read as: "A biological survey of water samples taken from the reservoir about 7 weeks after application also found almost no living zooplankton, considered to be unusual for this type of water body (NSW DECC, 2007b), noting that pre-application monitoring was not carried out."

Request 1.51

Section 6.2.6, page 37, last paragraph

"In Netherlands, Phoslock™, known as the "Flock & Lock" lake restoration technique, has been

applied to at least three lakes. All applications and monitoring were conducted by Institut Dr Nowak (IDN).”
Suggested change:
“In Netherlands, Phoslock™ has been applied to at least three lakes. All applications and monitoring were conducted by one or more of the following organizations: Phoslock Europe GmbH, Institut Dr Nowak (IDN) and the Aquatic Ecology Department of Wageningen University.”
Reason:
The change is more technically correct.

Decision 1.51
Variation approved.

NICNAS Response 1.51
Additional information will be incorporated in the report.

Request 1.52
Section 6.3.1, page 39, last sentence in section
“The estimated exposure to the environment from Phoslock™ applications to water bodies are based on the level of soluble or dissolved or ionic lanthanum.”
Suggested change:
“The estimated exposure to the environment from Phoslock™ applications to water bodies are based on the level of soluble or dissolved lanthanum, which does not necessarily correspond to the ionic or bioavailable La3+ found in solution.”
Reason:
- As in Point [Request] 12 in this document , the use of the term ‘dissolved’ interchangeably with ‘bioavailable’ is not appropriate, as it is well known that the filtered/dissolved concentration of metals are not necessarily a reflection of the concentrations of metal ions in solution responsible for aquatic toxicity (ANZECC 2000, pg. 7.4-2; Florence 1986; Bott 1996).

Decision 1.52
Variation approved.

NICNAS Response 1.52
Clarification will be included in the report.

Request 1.53
Section 6.3.3, page 40, first paragraph
“Significant release of dissolved lanthanum occurs from Phoslock™ granules in a wide variety of environmental waters 1-3 days after application as shown in Table 6.7. The mechanisms underlying the much higher than expected release of dissolved lanthanum from Phoslock™ granules in environmental waters are a function of the various water chemistry parameters as well as the equilibrium of ionic lanthanum binding with the bioavailable phosphorus.”
Suggested change:
“Higher than expected concentrations of dissolved lanthanum occur in a wide variety of environmental waters 0-3 days after application of Phoslock™ granules as shown in Table 6.7. The mechanisms underlying this are a function of the various water chemistry parameters as well as the equilibrium of ionic lanthanum binding with the bioavailable phosphorus.”
Reason:
- The suggested changes are more scientifically correct. It is unknown whether or not the dissolved lanthanum measurements are a result of ‘release’ from Phoslock™ or an artefact of measuring very small particulate Phoslock™ still suspended in the water column.
- Zero days of application should be used as the bottom end of the range, as most measurements of dissolved lanthanum were conducted on the day of application (i.e. day 0).

Decision 1.53
Variation approved.

NICNAS Response 1.53
Amended paragraph to be incorporated in the report.

Request 1.54

Section 6.3.3, page 40, second paragraph:
"The company has provided revised calculations for the release of lanthanum from Phoslock™ granules in an environmental water sample which concludes that 60% of contained lanthanum was released (dose rate 0.72 mg/L Phoslock™) (PWS, 2008a)."
Suggested deletion of sentence:
"The company has provided revised calculations for the release of lanthanum from Phoslock™ granules in an environmental water sample which concludes that 60% of contained lanthanum was released (dose rate 0.72 mg/L Phoslock™) (PWS, 2008a)."
Reason:

- The information in the above text has been misunderstood. The extract in the letter from Mr Eddie Edmunds (PWS, 2008a), stated the following:
  "...the aim of the spreadsheet was to calculate the total amount of La being applied to the water body minus the amount of La that will be bound within the first 48 hours after the application (at Fitzroy Falls). At a dose rate of 0.72 ppm the amount of La being added to the FF water body is 36 µg/L. Within the first 48hrs it is estimated that 25µg/L of La will be bound to FRP, leaving 11µg/L of dissolved La in the water column (available to bind with incoming FRP). Based on our lab work we estimate 60% of the 11µg/L is in dissolved form (see Figure 1)."

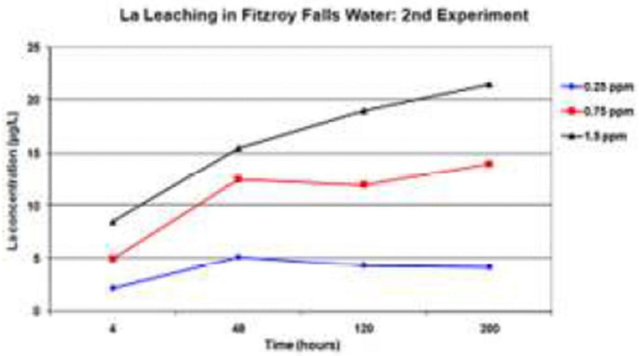

Figure1: Results from an in-house laboratory trial using Phoslock applied to water collected from Fitzroy Falls reservoir.

The calculations behind the above statement are as follows:

- The amount of La still in dissolved form was calculated to be 36Ng/L -25 Ng/L = 11 Ng/L. Mr Edmunds erroneously estimated that 60% of that (6Ng/L) would be in a dissolved form as ionic lanthanum.
- The estimate of 60% has not been substanciated and was purely speculative.
- In 2008 (at the time of Mr Edmunds' letter), there was no definitive way of distinguishing between the various forms of lanthanum that make up the "dissolved"La fraction. However recent testing conducted by Envirolab Services in February 2013 utilizing Chelex® analysis methods(see reference in PWS Reference section 3 a & b) has clarified composition levels of ionic lanthanum and compounds of lanthanum within the test water. A water sample containing Phoslock (43,000 mg/kg of La) was filtered through a 0.45 Nm filter. The concentration of La before the Chelex® analysis was 112 Ng/L (assuming this contains all forms of "dissolved La" such as particulate, colloidal etc). After presentation for Chelex® analysis, ionic lanthanum was detected at 1.5 Ng/L (approximately 1% of the dissolved amount).

Decision 1.54
Variation not approved.

NICNAS Response 1.54

In the correspondence cited, PWS was asked to comment on the calculations presented in a spreadsheet from the company entitled "Phoslock dose rates – Comparison with Fitzroy Falls – 17/6/08". This spreadsheet provided calculations for scenarios involving 100% and 60% release of lanthanum contained in Phoslock^{TM} following application of this chemical to the waters of Fitzroy Falls reservoir at a projected average dose rate of 0.72 mg Phoslock^{TM}/L.

The spreadsheet contains two footnotes related to the estimated final concentration of La in the Fitzroy Falls water after 48 hours (11 µg/L for 100% leaching after incorporating reactions with calculated phosphorus in the water column (*1) and 7 µg/L for 60% leaching after incorporating reactions with calculated phosphorus in the water column (*2)) which read as follows:

- *1 demonstrates the worst case scenario (highly unlikely) where 100% of the La is dissociated from Phoslock™.
- *2 demonstrates the most probable scenario where 60% of the La is dissociated from the Phoslock.

The estimate of 60% release of lanthanum from Phoslock^{TM} in Fitzroy Falls water appears consistent with results from the in-house leaching trial with Phoslock^{TM} applied to Fitzroy Falls water at a dose rate of 0.75 ppm (= 0.75 mg Phoslock^{TM}/L) as discussed in PWS Reference (2008a). In this in-house trial, the measured concentration of dissolved La was approximately 14 µg/L after 200 hours which is comparable with calculations by the company which indicate a maximum lanthanum concentration of 22 µg/L for 60% release of lanthanum into Fitzroy Falls waters from Phoslock^{TM} at a similar average dose rate of 0.72 mg Phoslock^{TM}/L.

Request 1.55

Section 6.3.3, page 41, Table 6.7

"91 (dissolved La)" for De Rauwbraken.

Suggested change:

28 (dissolved La)"

Reason:

- Text on page 38 states that filtered (dissolved) La at De Rauwbraken was 28 µg/L (van Oosterhout & Lurling, 2011).

Decision 1.55

Variation approved.

NICNAS Response 1.55

The entry in Table 6.7 will be changed.

Request 1.56

Section 6.3.4, page 42, first paragraph

"... the peak concentrations of lanthanum significantly exceeded the original estimate of 20 µg/L, ..."

Suggested change:

"... the peak dissolved concentrations of lanthanum significantly exceeded the original estimate of 20 µg/L,..."

Reason:

Provides additional clarity

Decision 1.56
Variation partially approved.

NICNAS Response 1.56
Slight change in the suggested text to read in the report as: "... the peak concentrations of dissolved lanthanum significantly exceeded the original estimate of 20 µg/L..."

Request 1.57

Section 6.3.4, page 42, second paragraph

"... this could explain the high level of peak dissolved lanthanum of 220 µg/L and the associated environmental impact."

Suggested change:

"... this could explain the high level of peak dissolved lanthanum of 220 µg/L."

Reason:

- It is unknown whether the environmental impact observed at the Deep Creek Reservoir was due to application of Phoslock™, a rapid pH change due to the application of soda ash, or something else.

Decision 1.57
Variation approved.

NICNAS Response 1.57
Report will be amended accordingly.

Request 1.58

Section 6.3.4, page 42, last paragraph

"Consequently, the maximum concentration of dissolved lanthanum that was measured in the waters of Deep Creek Reservoir following treatment with Phoslock™ (220 µg/L) will be used as an indicative figure of the peak environmental concentration of dissolved lanthanum that can occur in environmental waters after treatment with this chemical."

Suggested change:

"Consequently, the maximum concentration of dissolved lanthanum that was measured in the waters of Deep Creek Reservoir following treatment with Phoslock™ (220 µg/L) will be used as a conservative indicative figure of the peak environmental concentration of dissolved lanthanum that can occur in environmental waters after treatment with this chemical."

Reason:

- The application at Deep Creek used an abnormal dosing regime, i.e. three times the recommended dose.
- The second highest maximum concentration of dissolved lanthanum measured in any of the numerous field applications of Phoslock™ in Australia and overseas was 110 µg/L at Torrens Lake and Silbersee, Germany. This is half of what was measured as the maximum in a single sample at Deep Creek. It is also noteworthy that this peak concentration of dissolved lanthanum measured at Torrens Lake did not result in any major changes to macroinvertebrate and zooplankton community structure, and no obvious impacts on resident bird, fish or frog populations of the lake. This highlights the uncertainty in extrapolating the experimental information generated in laboratory toxicity tests with Phoslock™ to the field.
- The use of a maximum concentration, rather than another statistical measure (e.g. average or 95 per cent upper confidence limit), is conservative. It is unlikely, with the dilution and mixing of the water body, and the non-sedentary nature of most aquatic organisms, that exposure will occur to this peak concentration of dissolved lanthanum.

Decision 1.58
Variation approved.

NICNAS Response 1.58
Report will be amended to reflect this.

Request 1.59

Section 6.3.4, page 42, last paragraph

"Although it is possible that higher concentrations of dissolved lanthanum may occur in environmental waters with different chemical composition or following treatment at higher application rates based on the results of a series of laboratory jar tests, the more appropriate PEC determination is from actual field application results of the product."

Suggested change:

"Although the results of several laboratory tests (see Section 8.4) suggest that lower or higher concentrations of dissolved lanthanum may occur in waters with different chemical composition or following treatment at different application rates, the more appropriate PEC determination is from actual field application results of the product."

Reason:

- Ecotoxicity experiments with Phoslock™ doses ranging from 1 mg/L to 50,000 mg/L (i.e. approximately one tenth to 5,000 times the dose used at Deep Creek) have reported a range of measured dissolved lanthanum levels (20 – 820 µg/L) in various water types and at different dose levels (see study references for Table 8.1, pages 75-76).

Decision 1.59
Variation approved.

NICNAS Response 1.59
Amended text will be incorporated.

Request 1.60

Section 6.3.4, page 42, last paragraph

"For the purposes of risk characterisation, the peak dissolved lanthanum concentration of 220 µg/L is reasonably representative of the actual dissolved lanthanum concentrations following from Phoslock™ field applications and will be taken forward as the PEC in this assessment."

Suggested change:

"For the purposes of risk characterisation, the peak dissolved lanthanum concentration of 220 µg/L is reasonably representative of the maximum dissolved lanthanum concentration 0-3 days following a Phoslock™ field application and will be taken forward as the PEC for acute exposure in this assessment."

Reason:

- See rationale in Points [Requests] 16 and 18 of this document.
- If a chronic PNEC is used in the assessment as well, suggested additional text could be as follows: "The worst case PEC for chronic exposure would be a concentration of dissolved lanthanum 1-2 weeks after Phoslock™ application. The average of maximum dissolved lanthanum concentrations one week after various field applications was approximately 50 µg/L, which can be considered a PEC for chronic exposure (Table 5.1)."

Decision 1.60
Variation partially approved.

NICNAS Response 1.60
The word "acute" will not be included, for reasons discussed in Decisions 1.85 and 1.93; to maintain sentence flow it will be replaced by "lanthanum". Otherwise the amended text will be included.

Request 1.61

Section 8.2.2, page 68, second paragraph in section

"For weight-based growths ... the EC50 and NOEC were 1557 and 500 mg/L Phoslock™, respectively (Lürling & Tolman, 2010)."

Suggested change:

"For weight-based growths ... the EC50 and NOEC were 1557 and 500 mg/L Phoslock™, respectively (Lürling & Tolman, 2010). Authors speculated the observed effects were probably due to feeding inhibition by suspended clay particles, rather than direct toxicity of bioavailable lanthanum."

Reason:

- This provides more complete information on the possible reasons for the effects observed.
- The potential secondary effect of Phoslock™ or ionic lanthanum (which binds with available CO_3 or PO_4) reducing food availability for primary consumers (e.g. macroinvertebrates) in environmental waters is a potential explanation for why ecotoxicity is observed in some laboratory experiments. However, in environmental waters, recovery of aquatic ecosystems from a disturbance, such as secondary food limitation through treatment of eutrophication, is expected to occur relatively quickly (Niemi et al. 1990, Reynolds 2002, Power 1998).

Decision 1.61

Variation partially approved.

NICNAS Response 1.61

Statement will read as: "For weight-based growths ... the EC50 and NOEC were 1557 and 500 mg/L Phoslock™, respectively (Lürling & Tolman, 2010). The authors speculated that the observed effects were possibly due to feeding inhibition by suspended clay particles, rather than direct toxicity of bioavailable lanthanum."

Request 1.62

Section 8.2.2, page 68, last paragraph

"... For the Scanlon Pond solution, 42% mortality was observed at the highest dose, hence LC50 was given as >6.8 g/L Phoslock™ ..."

Suggested change:

"... For the Scanlon Pond solution, 42% mortality was observed at the highest dose, hence LC50 was given as >6.8 g/L Phoslock™. The author indicated that mortalities seen in Daphnia appeared to be caused by physical entrapment in Phoslock™ and some organisms physically trapped in the Phoslock™ slurry were alive upon test termination ..."

Reason:

- The above provides more clarity on the apparent effects observed.

Decision 1.62

Variation approved.

NICNAS Response 1.62

Additional text will be added in the report.

Request 1.63

Section 8.2.3, page 69, first paragraph

"At the end of the test duration, an increase in dissolved lanthanum from 10 to 14 µg/L occurred for a 5-fold increase in Phoslock™ dose (40-200 mg/L), while fish toxicity increased from 0 to 5%."

Suggested change:

It is suggested the above sentence be deleted.

Reason:

- This is an incorrect account of the acute fish fry study in Martin and Hickey (2004), since dissolved lanthanum was not measured, and the Phoslock™ doses given in the statement were not tested in this study.

Decision 1.63
Variation approved.

NICNAS Response 1.63
Statement will be deleted in that section of the report. The sentence was referring to a different study.

Request 1.64

Section 8.2.3, page 69, second paragraph
"The 96-hour LC50 determined for this test was >13.6 g/L Phoslock™."
Suggested change:
"No mortality was observed at any of the Phoslock™ concentrations tested. The 96-hour LC50 determined for this test was >13.6 g/L Phoslock™."
Reason:

- The above provides more clarity.

Decision 1.64
Variation approved.

NICNAS Response 1.64
Additional text will be added in the report.

Request 1.65

Section 8.2.3, page 69, third paragraph
"The 28-day LC50 for lanthanum to rainbow trout has been reported as 13-20 μg/L (US EPA, 2004), and presumably is less toxic over 4 days. Toxicity could be exacerbated by gill clogging by the settling Phoslock™ or precipitating lanthanum phosphate. The pH in the final solution was reported to be as high as 10, and this is likely to be an additional stressor. Toxicity due to aluminium dissolving from the sediment is likely at this pH. Dissolved lanthanum measurements were not reported."
Suggested change:
"The 28-day LC50 for lanthanum to rainbow trout eggs in a rapid toxicity screening study has been reported as 20 μg/L (Birge et al. 1978, 1979, 1980), and presumably is less toxic over 4 days."
Reason:

- The citation provided for the study is the US EPA Ecotoxicity database (cited in your report as US EPA 2004). The database was consulted by us on the 12th February, 2013. There is no ecotoxicity study listed reporting a 28-day LC50 for rainbow trout of 13 μg/L. Three 28-day LC50s are listed as 20 μg/L. The original papers (Birge et al. 1978, 1979, 1980) were consulted; all three report the same result (LC50 of 20 μg/L) of a single rapid 28-day toxicity screening study on rainbow trout eggs.
- The sentences that follow the first sentence do not relate to these results and should be deleted.

Decision 1.65
Variation approved.

NICNAS Response 1.65
The US EPA Ecotoxicity database and the databases of the OECD QSAR Toolbox (v 2.2) were checked on 3 March 2013 for all available fish toxicity data for lanthanum salts and only the end-points cited by the company were found. The data cited also appear in

Clearwater & Hickey (2004, p. 17), but the original figure of 13 µg/L can now no longer be found in the available databases.
Amended text will be included in the report.

Request 1.66

Section 8.2.3, page 69, fourth paragraph

"In the sediment study of Clearwater & Hickey (2004), O. mykiss was treated (up to 400 mg/L Phoslock™) and toxicity was observed in accordance with the Environment Canada method for determining acute lethality. Fish mortality increased from 0 to up to 50% between the 40 and 200 mg/L Phoslock™ treatments with a dissolved lanthanum increase of 10 to 14 µg/L. 100% mortality was observed at the highest dose with total lanthanum level of 88 µg/L (dissolved lanthanum not reported at this treatment). The 4-day rainbow trout LC50 and NOEC were 200 and 40 mg/L Phoslock™, respectively."

Suggested change:

"In the acute toxicity study of Clearwater & Hickey (2004), O. mykiss was treated (up to 400 mg/L Phoslock™) and toxicity was observed in accordance with the Environment Canada method for determining acute lethality. Test vessels contained a layer of sand in the base. Phoslock™ granules were preweighed and sprinkled evenly over the water surface. Fish mortality increased from 0 to up to 50% (although highly variable ± 45%) between the 40 and 200 mg/L Phoslock™ treatments, but dissolved lanthanum measured at the end of the test in these treatments was only 10 and 14 µg/L, respectively. 100% mortality was observed at the highest dose with total lanthanum level of 88 µg/L (dissolved lanthanum not reported at this treatment). The 4-day rainbow trout LC50 and NOEC were 200 and 40 mg/L Phoslock™, respectively. Authors of the study commented the data suggest either dissolved lanthanum is not primarily responsible for increased trout mortality or the dose response curve for dissolved lanthanum is very steep, because mortality rates changed markedly with only very small increases in dissolved lanthanum (~4 µg/L). Additionally, the pH in the final solution was reported to be as high as 10; this is likely to be an additional stressor. Toxicity due to aluminium dissolving from the sediment is also likely at this pH."

Reason:

- The additional descriptions have been reproduced partially from the third paragraph of this section, which was found to have been in the incorrect spot.
- The additional information also provides the reader with an appreciation of the uncertainties in the reason for the toxicity observed in the test.

Decision 1.66

Variation approved.

NICNAS Response 1.66

The reorganisation of text is considered acceptable in view of the changes made under decision 1.65 above.
Amended text will be included in the report.

Request 1.67

Section 8.2.3, page 69, end of section

Suggested change:

Suggested to add in the following text at the end of section 8.2.3:

"The sub-acute toxicity of dissolved lanthanum from Phoslock™ or soluble lanthanum salts to other fish species seems to be much lower with 96-hour E(L)C50s ranging from >127 µg/L in rainbow fish (Stauber 2000) to 23,000 µg/L in zebrafish (RIVM 2000)."

Reason:

- Numerous sub-acute toxicity tests have been conducted in other fish species using Phoslock™ or soluble lanthanum salts, which have shown no toxicity at much higher concentrations of dissolved lanthanum. The additional information provides a more balanced summary of the available information for fish, rather than simply providing data for rainbow trout alone.

Decision 1.67
Variation approved.

NICNAS Response 1.67
Suggested sentence will be slightly amended combined with supporting analysis. The additional analysis will indicate that Phoslock™ toxicity is more dependent on water chemistry parameters than on the existence of sensitive species of the receiving waters. Reference to RIVM (2000) will also be included in the report. Additions will appear as a new paragraph to read as:
"The sub-acute toxicity of dissolved lanthanum from Phoslock™ or soluble lanthanum salts to other fish species seems to be much lower with 96-hour E(L)C50s ranging from >127 µg/L in rainbow fish (Stauber 2000) to 23,000 µg/L in zebrafish (RIVM 2000). The shortcomings demonstrated in the rainbow trout data, which indicate that apparent toxicity varies by orders of magnitude depending on water chemistry are also expected to apply in these studies. It is not possible to clearly identify sensitive species from these results."

Request 1.68
Section 8.2.4, page 69, first paragraph
"... amphipod Phreatogammarus hemsii, and worm ..."
Suggested change:
"... amphipod Phreatogammarus helmsii, and worm ..."
Reason:
- This is the correct spelling of the amphipod species name.

Decision 1.68
Variation approved.

NICNAS Response 1.68
Species name will be corrected all throughout the report.

Request 1.69
Section 8.2.4, page 69, second paragraph
"The mortality of P. hemsii increased from 20 to 70% in Phoslock™ doses of 20-40 mg/L with corresponding dissolved lanthanum levels of 6-8 µg/L. The authors stated that the amphipod mortality may not be due to lanthanum toxicity alone."
Suggested change:
"The mortality of P. helmsii increased from 20 to 70% in Phoslock™ doses of 20-40 mg/L with corresponding dissolved lanthanum levels of 6 and 8 µg/L, respectively, measured at the end of the test. Authors of this study commented the mortality observed in the test may have been due to physical effects rather than direct toxicity of bioavailable lanthanum."
Reason:
- *P. helmsii* is the correct spelling of the amphipod species name.
- The additional information also provides the reader with an appreciation of the uncertainties in the reason for the toxicity observed in the test.

Decision 1.69
Variation partially approved.

NICNAS Response 1.69
Statement will read as: "The mortality of *P. helmsii* increased from 20 to 70% in Phoslock™ doses of 20-40 mg/L with corresponding dissolved lanthanum levels of 6-8

µg/L measured at the end of the test. Authors of this study suggested that the mortality observed may be due to physical effects rather than direct toxicity of bioavailable lanthanum."
A brief discussion of the types of physical effects seen in the aquatic toxicity studies, together with a statement on the variability of the results, will be included at the end of Section 8.1.

Request 1.70

Section 8.2.4, page 70, second paragraph

"The 38-day LC50 and NOEC were >400 and 400 mg/L Phoslock™, respectively (for both survival and emergence)."

Suggested change:

"No toxicity was observed throughout the test, so the 38-day LC50 and NOEC were >400 and 400 mg/L Phoslock™, respectively (for both survival and emergence)."

Reason:

- This makes what was found in the study more explicit, and provides additional clarity to the reader.

Decision 1.70

Variation approved.

NICNAS Response 1.70

Additional clarity will be reflected in the report.

Request 1.71

Section 8.3, page 71, first paragraph

"Measured lanthanum concentrations in the 48-hour test ranged from 15 µg/L for a 0.75 mg/L Phoslock™ application, to 480 µg/L for 50 mg/L Phoslock™. It was argued that some of this high concentration could have been filterable but particulate (or colloidal). The highest lanthanum level in the chronic test was 20 µg/L for a 1 mg/L Phoslock™ application."

Suggested change:

"Measured dissolved lanthanum concentrations in the 48-hour test ranged from 15 µg/L for a 0.75 mg/L Phoslock™ application, to 480 µg/L for 50 mg/L Phoslock™. It was argued that some of this high concentration could have been filterable but particulate (or colloidal). The highest dissolved lanthanum level in the chronic test was 20 µg/L for a 1 mg/L Phoslock™ application."

Reason:

- Dissolved lanthanum was measured in this test.

Decision 1.71

Variation approved.

NICNAS Response 1.71

Additional text will be added in the report.

Request 1.72

Section 8.3, page 71, second paragraph

"Similar results were obtained for both samples, with an EC50 value in the range 150-160 µg/L La, and with immobilisation occurring at 170 µg/L La with a LOEC of 20 mg/L Phoslock™. This is inconsistent with the ESA results on the Fitzroy Falls water which showed no toxicity at 330-480 µg La/L (50 mg/L Phoslock™)."

Suggested change:

"Similar results were obtained for both samples, with a LOEC of 20 mg/L Phoslock™, and a NOEC

of 10 mg/L. Lanthanum levels were not reported."
Reason:
- The reference cited (NSW DECC 2008b) does not provide results for lanthanum levels in the test vessels.

Decision 1.72
Variation not approved.

NICNAS Response 1.72
The report cited contains the results of acute toxicity tests of Phoslock^{TM} granules to *Ceriodaphnia dubia* in Fitzroy Falls Reservoir water conducted by the DECC Ecotoxicology Laboratory on 1 September 2008. Table 1 of this report provides lanthanum concentrations (filterable) expressed in µg/L measured at test initiation for toxicity tests conducted at nominal application rates up to 100 mg Phoslock^{TM}/L.

Request 1.73
Section 8.3, page 72, fourth paragraph
"The reported EC50 values for D. magna and fish egg toxicity were 103 and 105 mg/L La^{3+}*, respectively (IDN, 2008a and 2008b)."*
Suggested change:
"The reported EC50 values for D. magna and fish egg toxicity were 103 and 150 mg/L La^{3+}*, respectively (IDN, 2008a and 2008b)."*
Reason:
- The cited reports both provide an EC50 of 150 mg/L, not 105 mg/L, for toxicity to fish eggs.

Decision 1.73
Variation approved.

NICNAS Response 1.73
This will be corrected in the report.

Request 1.74
Section 8.4, page 73, last sentence
"Toxic effects associated with Phoslock™ are most likely due to dissolved lanthanum released to the overlying water as the surface applied granules or granule slurry settle through the water column to the sediment."
Suggested change:
"Toxic effects associated with Phoslock™ in laboratory experiments are most likely due to bioavailable lanthanum released to the overlying water as the surface applied granules or granule slurry settle through the water column to the sediment, although in some tests, toxicity may have been due to physical effects of Phoslock™ or food limitation."
Reason:
- It is important to reiterate that this statement is referring to the toxicity observed in laboratory experiments.
- Several studies have concluded toxicity observed may have been due to either physical (i.e. entrapment) effects of the Phoslock™ granules or food limitation due to a precipitation of Phoslock™ and phosphorus in the medium (Watson-Leung 2009, Stauber and Binet 2000, Clearwater and Hickey 2004).

Decision 1.74
Variation approved.

NICNAS Response 1.74
Statement in the report will be amended to reflect the suggestion.

Request 1.75
Section 8.4, page 74, last paragraph
"... immobilisation of C. dubia (ESA, 2008), ..."
Suggested change:
"... immobilisation and reproduction of C. dubia (ESA, 2008), ..."
Reason:
- The ESA (2008) reference also examined the effects of Phoslock™ on reproduction of *C. dubia.*

Decision 1.75
Variation approved.

NICNAS Response 1.75
This will be added to the report.

Request 1.76
Section 8.4, page 76, Table 8.1

"*O. mykiss*	4	Phoslock (Eureka)	33-51	**200** mg/L Phoslock	**10 - 14**	Clearwater & Hickey, 2004"

Suggested change:

"*O. mykiss*	4	Phoslock (Eureka)	33-51	**200** mg/L Phoslock	**14**	Clearwater & Hickey, 2004"

Reason:
- The measured concentration of dissolved lanthanum at the end of the test in the vessel containing the EC50 Phoslock™ dose of 200 mg/L was 14 µg/L, not 10 µg/L.

Decision 1.76
Variation approved.

NICNAS Response 1.76
Amended value will be included in the Table.

Request 1.77
Section 8.4, page 76, Table 8.1

"*O. mykiss*	28	NR	NR	**20** µg/L La	NR	US EPA, 2004"

Suggested change:

"*O. mykiss*	28	NR	NR	**20** µg/L La	NR	Birge et al. 1978, 1979, 1980"

Reason:
- The correct references for the original studies are Birge et al. (1978, 1979, 1980)
- Also refer to Request 65 where it explains that the citation provided for the study is the US EPA Ecotoxicity database (cited in your report as US EPA 2004). The database was consulted by us on the 12th February, 2013. There is no ecotoxicity study listed reporting a 28-day LC50 for rainbow trout of 13 Ng/L. Three 28-day LC50s are listed as 20 Ng/L. The original papers (Birge et al. 1978, 1979, 1980) were consulted; all three report the same result (LC50 of 20 Ng/L) of a single rapid 28-day toxicity screening study on rainbow trout eggs.

Decision 1.77
Variation approved.

NICNAS Response 1.77
Amended reference will be included in the Table.

Request 1.78

Section 8.4, page 76, Table 8.1

"*Phreatog ammarus hemsii*	10	Phoslock (Eureka)	>70	**33** mg/L Phoslock	**6 - 8**	Clearwater & Hickey, 2004"

Suggested change:

"*Phreatog ammarus helmsii*	10	Phoslock (Eureka)	>70	**33** mg/L Phoslock	**Approx. 8 (or lower)**	Clearwater & Hickey, 2004"

Reason:

- The correct spelling of the amphipod species name is *P. helmsii*.
- The concentration of dissolved lanthanum at the end of the test in the vessel containing the NOEC Phoslock™ dose of 20 mg/L was 6µg/L, therefore the EC50 Phoslock™ dose of 33 mg/L could not have also been 6 µg/L, unless toxicity observed was not due to bioavailable lanthanum. This could be construed as a reason for not using this study to determine a PNEC for Phoslock™, since there is considerable uncertainty associated with it.

Decision 1.78
Variation partially approved.

NICNAS Response 1.78
Corrected spelling of the test species accepted.
The 10-day NOEC for *Phreatogammarus helmsii* is less than 20 mg Phoslock^{TM}/L as reported by Clearwater & Hickey (2004). The 10-day LC50 of 33 mg Phoslock^{TM}/L (or 6–8 µg La/L) is therefore not necessarily in conflict with the data reported in the study. The response curve for this test also indicates a strong dependence on the applied dose of Phoslock^{TM} in the range of the deduced LC50. A more detailed analysis of the response curve in terms of dissolved lanthanum is limited by the study design which did not determine responses below the LOEC (20 mg Phoslock^{TM}/L).

Request 1.79

Section 8.4, page 77, last paragraph

"... the invertebrate P. hemsii ..."

Suggested change:

"... the invertebrate P. helmsii ..."

Reason:

- This is the correct spelling.

Decision 1.79
Variation approved.

NICNAS Response 1.79
Species name will be corrected all throughout the report.

Request 1.80

Section 8.4, page 77, last paragraph

"At this applied dose, the concentration of dissolved lanthanum is 6-8 µg/L."

Suggested change:

"At these doses, the concentrations of dissolved lanthanum measured at the end of the test were approximately 8 (or lower) and 6 µg/L, respectively."

Reason:

- This is a more appropriate manner of wording this.

Decision 1.80

Variation approved.

NICNAS Response 1.80

Amended text will be included in the report.

Request 1.81

Section 8.5, page 79, dot points

"Invertebrate: 2d EC50 – 33 mg/L Phoslock™ (6-8 µg/L dissolved La)"

Suggested change:

"Invertebrate: 2d EC50 – 33 mg/L Phoslock™ (8 µg/L dissolved La or less)
2d NOEC – 20 mg/L Phoslock™ (6 µg/L dissolved La)"

Reason:

- The dissolved lanthanum concentration measured at the quoted NOEC for Phoslock™ of 20 mg/L was 6 µg/L, and the dissolved concentrations measured in the next highest loading of Phoslock™ was 8 µg/L. Therefore the dissolved concentration at the EC50 of 33 mg/L Phoslock™ cannot be 6 Ng/L, unless toxicity observed was not due to bioavailable lanthanum. This could be construed as a reason for not using this study to determine a PNEC for Phoslock™, since there is considerable uncertainty associated with it.

Decision 1.81

Variation not approved.

NICNAS Response 1.81

Refer to Decision 1.78. Note that the entry will be corrected to "10-day EC50"

Request 1.82

Section 8.5, page 79, dot points

"Fish: 4d EC50 – 200 mg/L Phoslock™ (10-14 µg/L dissolved La)"

Suggested change:

"Fish: 4d EC50 – 200 mg/L Phoslock™ (14 µg/L dissolved La)"

Reason:

- The dissolved lanthanum concentration measured at the quoted EC50 for Phoslock™ of 200 mg/L was 14 µg/L, not 10 µg/L.

Decision 1.82

Variation approved.

NICNAS Response 1.82

Amended value will be included. Note that the entry will be corrected to "4-day LC50"

Request 1.83

Section 8.5, page 79, last paragraph

"Based on the lowest dissolved lanthanum level of 6 µg/L in equilibrium with an acute Phoslock™ EC50 of 33 mg/L, a freshwater low reliability trigger value for ionic lanthanum was derived using the assessment factor of 100 and could be revised to 0.06 µg/L. This value is considered comparable to a PNEC in this assessment, but it has not been calibrated for the influence of water chemistry."

Suggested change:

"Based on the lowest dissolved lanthanum level of approximately 6 µg/L in equilibrium with an acute Phoslock™ NOEC of 20 mg/L, a freshwater low reliability (i.e. high uncertainty) trigger value for ionic (i.e. bioavailable) lanthanum was derived using the assessment factor of 100 and could be revised to 0.06 µg/L. This value is considered comparable to a PNEC for chronic exposure in this assessment, but it has not been calibrated for the influence of water chemistry. The equivalent low-reliability PNEC appropriate for acute exposure would be 0.6 µg/L for bioavailable lanthanum."

Reason:

- See rationale in Points [Requests] 16, 18 and 81 in this document.

Decision 1.83

Variation not approved.

NICNAS Response 1.83

It is generally accepted that high reliability PNECs (or trigger values) derived from high quality NOECs from multiple chronic toxicity studies provide more reliable indicators for acceptable levels of toxicants in aquatic ecosystems. However, there are currently insufficient long term aquatic toxicity data for both lanthanum and Phoslock™ that have been calibrated for the effects of water chemistry to allow these high reliability PNECs to be determined. The development of site-specific trigger values for Phoslock™ and lanthanum with specifically focussed testing requirements is considered an interim solution until more reliable PNECs with adequate predictive power for risk assessment can be developed.

As a general concept it is acceptable to rely on acute ecotoxicity data to derive a Predicted No Effect Concentration where there are insufficient reliable chronic aquatic toxicity data available. The PNEC is intended to provide a conservative estimate of the concentration level that will not cause any unacceptable effects (both short and long-term) in an aquatic ecosystem exposed to a toxicant.

Request 1.84

Section 9.4, Page 82, third paragraph

"... concentration of lanthanum in drinking water should not exceed...."

Suggested change:

"... concentration of lanthanum in drinking water at the tap should not exceed...."

Reason:

- The suggested change makes it explicit that the water concentration for the 'controlled scenario' relates to 'at tap' drinking water concentrations. It is not a goal for lanthanum in source waters.

Decision 1.84

Variation partially approved.

NICNAS Response 1.84

Slightly amended to read as: "... concentration of lanthanum in drinking water as supplied to the consumer should not exceed...."

Request 1.85

Section 9.4, Page 83, estimation of margins of exposure, second paragraph

"The ingestion exposure of soluble lanthanum was determined using controlled and reasonable worst-case concentrations of 2 and 33 µg/L, respectively, of lanthanum in drinking water."

Suggested change:

"The ingestion exposure of soluble lanthanum was determined using 'controlled 'and 'worst-case' assumed concentrations of 2 and 33 µg/L, respectively, of lanthanum in drinking water at the tap."

Reason:

- The word 'reasonable' has been deleted because it is highly unlikely concentrations of 33 Ng/L will be 'at tap' after polishing treatments of source water (Section 9.4).
- 'assumed' is added to clarify that these concentrations are not measured 'at tap' concentrations nor concentrations that would necessarily be expected.
- inclusion of 'at tap' makes it explicit regarding what water is being assessed (see also paragraph 3 of this section).

Decision 1.85

Variation partially approved.

NICNAS Response 1.85

Statement will read as: "The ingestion exposure of soluble lanthanum was determined using controlled and reasonable worst-case concentrations of 2 and 33 µg/L, respectively, of lanthanum in drinking water as supplied to the consumer."

Request 1.86

Section 9.4, Page 83, estimations of margins of exposure, second paragraph

"The MOE was calculated based on the NOAEL of 0.1 mg/kg bw/day for children and 2 mg/kg bw/day for adults and ..."

Suggested change:

"The MOE was calculated based on the NOAEL of 0.06 mg/kg bw/day for children and 1.2 mg/kg bw/day for adults and ..."

Reasons:

- Clarification required; the report details the derivation of 0.1 mg/kg/d and reads as if this is a NOAEL value for all population sections. While there is not necessarily disagreement with the choice of 2 mg/kg/d for adults it is not described in the report how this value was determined.
- The oral intake is for soluble lanthanum (i.e. lanthanum ions) hence this should be compared with the lanthanum dose and not with a dose of lanthanum chloride. The NOAELs have therefore been adjusted according to the lanthanum content of lanthanum chloride but not accounting for hydration water (MW La/MW $LaCl_3$ = 139/245.5 = 0.566).

Decision 1.86

Variation approved.

NICNAS Response 1.86

The clarification on the choice of the critical NOAEL for adults and children will be reflected on the first paragraph of page 82 in the report to read as:
"The studies in Table 9.1 support a NOAEL for brain biochemistry and neurodevelopmental effects from lanthanum chloride in the dose range of 0.1–11 mg/kg bw/day. Within this range, the appropriate NOAELs for risk estimation are: 2 mg/kg bw/day for adults from brain biochemistry changes in adult rats (Feng et al., 2006b) and 0.1 mg/kg bw/day for children from neurobehavioural changes observed in rat pups (He et al., 2008)."
In addition, the NOAELs will be adjusted to reflect the ionic lanthanum dose and not of lanthanum chloride. The second paragraph will be amended to read as:
"The NOAELs to be used for risk estimation are adjusted according to the ionic lanthanum

content of lanthanum chloride but not accounting for hydration of water (MW La / MW LaCl3 = 0.566). The MOE was calculated based on the NOAEL of 0.06 mg/kg bw/day for children and 1.2 mg/kg bw/day for adults and ...”

Request 1.87

Section 9.4, Page 83, Table 9.2

“Table 9.2. Risk parameters and calculated MOE from estimated ingestion exposure to drinking water of adults and children.

	NOAEL (mg/kg bw/day)	I_{oral} (µg/kg bw/day) Controlled	Worst-case	MOE Controlled	Worst-case
Child	0.1	0.2	3.3	**500**	**30**
Adult	2	0.06	0.94	**33333**	**2128**

Suggested change:

“Table 9.2. Risk parameters and calculated MOE from estimated ingestion exposure to drinking water of adults and children.

	NOAEL (mg/kg bw/day)	I_{oral} (µg/kg bw/day) Controlled	Worst-case	MOE Controlled	Worst-case
Child	0.06	0.02	0.33	**3,000**	**182**
Adult	1.2	0.006	0.094	**183,333**	**11,702**

Reasons:

- NOAELs have been changed as per Request 86 in this document.
- I_{oral} has been changed as per Request 47 in this document.
- MOEs have been recalculated accordingly.

Decision 1.87

Variation partially approved.

NICNAS Response 1.87

Following on the revised calculations as a consequence of Decisions 1.47 and 1.86, received oral dose remains the same and NOAELs adjusted, the MOE calculations will be amended to:

Table 9.2. Risk parameters and calculated MOE from estimated ingestion exposure to drinking water of adults and children.

	NOAEL (mg/kg bw/day)	D_{oral} (µg/kg bw/day) Controlled	Worst-case	MOE Controlled	Worst-case
Child	0.06	0.2	3.3	**300**	**18**
Adult	1.2	0.06	0.94	**20000**	**1277**

Request 1.88

Section 9.4, Page 83, estimations of margins of exposure, third paragraph

“The risk estimates for the controlled exposures of children and adults are above 100 and hence indicate low risk of adverse developmental effects. However, the MOE for the reasonable worst case scenario is significantly less than 100 for children and marginal for adults”.

Suggested change:

“The risk estimates for the controlled exposures of children and adults, and the worst case scenarios are above 100 and hence indicate low risk of adverse effects”.

Reason:

- The change (deletion of the 2nd sentence) reflects the outcome of Request 87.

- ‘developmental’ has been deleted because the term is generally understood to be for toxicological outcomes connected with exposure *in utero* and therefore not applicable to already developed children or adults. The NOAELs are the lowest available from the data set and so inherently cater for a range of potential health effects potentially associated with higher exposures.

Decision 1.88
Variation not approved.

NICNAS Response 1.88
Although adjustments were made to the NOAELs, the risks remained the same (see revised Table 9.2 in Response 1.87).

Request 1.89
Section 9.4, Page 84, uncertainties in the risk assessment, first dot point
“Absence of Phoslock™-specific data for oral bioavailability’
Suggested change:
“Absence of specific data for oral bioavailability of lanthanum from Phoslock™.”
Reason:
- The existing statement does not articulate the specific uncertainty, indeed the statement is nonsensical.

Decision 1.89
Variation approved.

NICNAS Response 1.89
Statement will be revised accordingly.

Request 1.90
Section 9.4, Page 84, uncertainties in the risk assessment, third dot point
“Lack of data on the health effects of Phoslock™ in young and/or adult humans following acute and/or repeated exposures”;
Suggested change:
- Delete

Reason:
- It is toxicologically nonsensical to suggest acute or repeat dose studies be undertaken with a product that is 95% bentonite clay. The predictable outcome is blockage of the intestinal tract at moderate to high doses, and at doses that do not cause such morbidity there will be significant nutritional imbalance with repeat doses.

Decision 1.90
Variation partially approved.

NICNAS Response 1.90
To provide more clarity, the sentence will be amended as: “Lack of data on the health effects of lanthanum released from Phoslock™ in young and/or adult humans following acute and/or repeated exposures;”

Request 1.91

Section 9.4, Page 84, uncertainties in the risk assessment, last dot point

"These data gaps contribute to the uncertainty in the risk estimates of Phoslock™ toxicity in humans.

Suggested change:

- Delete

Reason:

- This statement is not an uncertainty *per se* but is an outcome of the data uncertainties. It also is a reiteration of the second sentence in paragraph 1.

Decision 1.91

Variation approved.

NICNAS Response 1.91

Sentence will be deleted.

Request 1.92

Section 9.4, Page 84, uncertainties in the risk assessment

"There is a high degree of uncertainty associated with the estimates of the reasonable worst-case exposures, as it is not known whether the concentration of soluble lanthanum in Phoslock™-treated waters eight weeks post-application is the actual concentration that will be present in the drinking water to be available to the Australian population.

Areas of concern

The assumptions used for the reasonable worst-case exposures may lead to overestimation of risk to the population. The sensitivity of individuals and subpopulations to the critical health effects associated with lanthanum exposure may vary significantly as demonstrated by the studies in animals manifesting neurotoxic and neurobehavioural effects".

Suggested change:

"There is a high degree of uncertainty associated with the estimates of the reasonable worst-case exposures, as it is not known whether the concentration of soluble lanthanum in Phoslock™-treated waters eight weeks post-application is the actual concentration that will be present in the drinking water to be available to the Australian population. The assumptions used for the reasonable worst-case exposures may lead to overestimation of risk to the population.

Areas of concern

~~The assumptions used for the reasonable worst-case exposures may lead to overestimation of risk to the population.~~ The sensitivity of individuals and subpopulations to the critical health effects associated with lanthanum exposure may vary significantly. ~~as demonstrated by the studies in animals manifesting neurotoxic and neurobehavioural effects~~".

Reason:

- 'reasonable' has been deleted as per Request 85.
- The last part of the last sentence has been deleted because the toxicological data does not show different sensitivity between animals (species). The same test protocol, investigating the same end points with the same lanthanum compound has not been undertaken for neonates or adults of different species. The pivotal study has exposure *in utero,* during lactation (neonate) and as a juvenile. Data is not available to determine which of these life stages is more sensitive to the neurobehavourial effects.

Decision 1.92

Variation approved.

NICNAS Response 1.92

Suggested change will be reflected in the report.

Request 1.93

Section 9.4, Page 84, uncertainties in the risk assessment, last paragraph

"There are no known standard treatment protocols employed uniformly by the state and territory authorities. However, it is possible that lanthanum levels may be reduced by the processes used to prepare potable water fit for human consumption and adhering to the recommended levels of the Australian Drinking Water Guidelines. In addition, lanthanum levels in drinking water need to be managed so as not to present risk of adverse developmental effects."

Suggested change deletion of above paragraph and replacement with:

"There are no known standard treatment protocols employed uniformly by the state and territory authorities. However, it is expected that lanthanum levels may be reduced by the processes used to prepare potable water fit for human consumption and adhering to the recommended levels of the Australian Drinking Water Guidelines. In addition, lanthanum levels in drinking water need to be managed so as not to present risk of adverse developmental effects. There are relatively few instances in Australia where treatment and polishing of drinking water is not undertaken and, generally, water treatment processes consist of various stages treatment each designed to improve and enhance water clarity and purity. The most widely applied process of potable water treatment is a combination of some or all of the following consisting of coagulation, flocculation and sedimentation, filtration, pH correction and anti-scaling chemicals and has been used routinely for water treatment since the early part of the twentieth century.[(4)] [(5)] Residues of compounds of lanthanum modified bentonite (Phoslock™), lanthanum phosphate ($LaPO_4$) and other particulate bound lanthanum which may form part of the total suspended solids load are expected to be removed during the commonly used treatments processes of filtration and flocculation/coagulation. Anticipated concentrations of lanthanum at the tap are projected to be below levels of detection due to commonly used water treatment processes where the lanthanide compounds, as suspended solids, are removed along with general suspended solids loads. Lanthanum ions present in WTP feedwater can also be scavenged by pH correction and buffering chemicals, typically soda ash and calcium carbonate, by anti-scaling chemicals, typically phosphoric acid [(6)] and by the abundance of concentrated levels of phosphate present in filtration and flocculation circuits."

Reason:

- The various water treatment methods deployed at Drinking Water Treatment Plants, as described, offer a plausible means of polishing residual lanthanum that may remaining in the WTP feedwater.
- References (4), (5) and (6) are located in PWS Reference Documents list at the end of this report.

Decision 1.93

Variation partially approved.

NICNAS Response 1.93

Additional information is summarised and will be added in this paragraph to read as: "There are no known standard treatment protocols employed uniformly by the state and territory authorities. However, it is expected that lanthanum levels will be reduced by the processes used to prepare potable water fit for human consumption (e.g. coagulation, flocculation, sedimentation, filtration, pH correction, anti-scaling, or a combination of these) and adhering to recommended maximum levels obtained by using the standardised methodology of the Australian Drinking Water Guidelines. Residues of compounds of lanthanum modified bentonite (Phoslock™), lanthanum phosphate ($LaPO_4$) and other particulate bound lanthanum which may form part of the total suspended solids load are expected to be removed during the any of these processes. In addition, lanthanum levels in drinking water provided to the customer need to be monitored and managed so as not to present risk of adverse developmental effects."

Request 1.94

Section 10.2, page 85, first sentence in section

"The environmental effects of Phoslock™ are principally derived from the dissolved or ionic lanthanum ..."

Suggested change:
"The environmental effects of Phoslock™ are likely to be principally derived from the ionic (i.e. bioavailable) lanthanum ..."
Reason:
- Toxicity experiments have shown high variability and uncertainty in results, and authors have speculated toxicity of Phoslock™ may also be related to physical effects or indirect toxicity due to food limitation.
- Dissolved lanthanum may not be reflective of bioavailable (i.e. ionic) lanthanum concentrations (see also rationale in Request 12 where it states that the use of the term 'dissolved' interchangeably with 'bioavailable' is not appropriate, as it is well known that the filtered/dissolved concentration of metals are not necessarily a reflection of the concentrations of metal ions in solution responsible for aquatic toxicity (ANZECC 2000, pg. 7.4-2; Florence 1986; Bott 1996)).

Decision 1.94
Variation approved.

NICNAS Response 1.94
Suggested change will be incorporated.

Request 1.95
Section 10.2.1, page 85, first paragraph
"... where the PNEC for lanthanum is 0.06 µg/L."
Suggested change:
"... where the conservative PNEC for acute exposure to bioavailable lanthanum is 0.6 µg/L. It is important to note the peak concentration of 220 µg/L measured at Deep Creek is the result of abnormal dosing (3x the recommended application rate), and is often more than double the maximum dissolved lanthanum concentrations measured on the day of application at any other water body dosed with Phoslock™ (10-110 µg/L)."
Reason:
- See Point [Request] 16 where the rationale is that it should be made clear that the derived PNEC is for chronic exposure, since an assessment factor of 100 was applied to the acute amphipod NOEC. The assessment factor of 100 includes: 1) a general uncertainty factor of 10 multiplied by 2) a default acute-to-chronic ratio of 10. The latter signifies that the derived PNEC is for chronic exposure. And also in the environmental risk assessment (see also rationale in Request 18), the PNEC for chronic exposure was directly compared to a peak (i.e. maximum) concentration of dissolved lanthanum measured shortly after application. This is inappropriate. Many national and international guidance documents for risk assessment state that the characterisation of risk associated with chemical exposures should be done using a toxicity reference value (in this case the chronic PNEC) that is commensurate with the length of exposure (e.g. WHO 1999, US EPA 1989, ATSDR 2005, WHO 2010, enHealth 2012a). Therefore, it would be more appropriate to compare the chronic PNEC to a predicted environmental concentration 1-2 weeks after Phoslock™ application. An *acute* PNEC may be used for comparison to a peak (i.e. maximum) concentration, and this rationale has been carried forward in later points.
- The additional text regarding the PEC places this concentration in context with what has been observed at other water bodies dosed at the recommended Phoslock™ dosing rate.

Decision 1.95
Variation not approved.

NICNAS Response 1.95
The PNEC has not been derived solely for a short term exposure scenario. As discussed under decision 1.83, the PNEC is intended to provide a conservative estimate of the concentration level that will not cause any unacceptable effects (both short and long-term) in an aquatic ecosystem exposed to a toxicant.
It is acknowledged in the report that the risk characterisation may overestimate the risks

from ionic lanthanum. However, it also noted that both short and long term toxic effects of ionic lanthanum on aquatic life appear strongly dependent on site specific water chemistry factors. In the absence of comprehensive aquatic toxicity models for lanthanum, such as acute and chronic biotic ligand models, it is not currently appropriate to set separate threshold values for short and long term effects of lanthanum and Phoslock™ in predictive risk assessment. It is also noted that the high bioaccumulation potential of lanthanum in aquatic invertebrates introduces an additional element of uncertainty into the risk characterisation, which further justifies the use of conservative extrapolation methods when deriving PNECs from a limited set of primarily acute ecotoxicity data.

Request 1.96

Section 10.2.1, page 85, first paragraph

"Based on this approach, the exceptionally high RQ for Phoslock™ is 3667."

Suggested change:

"Based on this approach, the resulting RQ for acute exposure to Phoslock™ is 367."

Reason:

- Using the suggested adjusted PNEC for acute exposure together with the conservative PEC from Deep Creek gives a revised RQ of 367 for acute effects.

Decision 1.96

Variation not approved.

NICNAS Response 1.96

Refer to Decisions 1.83 and 1.95.

Request 1.97

Section 10.2.1, page 85, first paragraph

"If the highest leaching rate of 20 µg/L dissolved lanthanum in laboratory tests identified in the original assessment (NICNAS, 2001) was taken as the PEC, RQ is 333."

Suggested change:

"If the highest leaching rate of 20 µg/L dissolved lanthanum in laboratory tests identified in the original assessment (NICNAS, 2001) was taken as the PEC, RQ for acute exposure is 33."

Reason:

- Using the suggested revised PNEC for acute exposure of 0.6 µg/L gives a RQ of 33.

Decision 1.97

Variation not approved.

NICNAS Response 1.97

Refer to Decisions 1.83 and 1.95.

Request 1.98

Section 10.2.1, page 85, first paragraph

"The latter calculation indicates a high risk of acute toxic effects on aquatic ecosystems ...."

Suggested change:

"The latter calculation indicates a potential risk of acute toxic effects on sensitive aquatic organisms ..."

Reason:

- The suggested revised RQ suggests there is a potential risk of acute toxic effects, but the RQ is no longer as high as it was previously.
- Use of the words 'sensitive aquatic organisms' is more explicit than the use of the word

'ecosystems'

Decision 1.98
Variation approved.

NICNAS Response 1.98
Statement will be amended in the report.

Request 1.99
Section 10.2.1, page 85, last paragraph
"At an exposure concentration of 220 µg/L of dissolved lanthanum in soft environmental water, all sensitive zooplankton would be expected to die within 48 hours based on the lowest measured EC50 of 43 µg La/L for water fleas in soft water from the study of Barry & Meehan (2000). This is consistent with environmental monitoring of Deep Creek Reservoir after application of Phoslock™ which showed almost no living zooplankton about 7 weeks following the trial."
Suggested change:
"Assuming an exposure concentration of 220 µg/L of dissolved lanthanum was uniformly distributed in a soft environmental water body, most sensitive zooplankton would be expected to die within 48 hours based on the lowest measured EC50 of 43 µg La/L for water fleas in soft water from the experimental laboratory study of Barry & Meehan (2000). In reality, however, it is considered unlikely this maximum dissolved lanthanum concentration would be uniformly distributed throughout the water body. Even though environmental monitoring of Deep Creek Reservoir after application of Phoslock™ showed almost no living zooplankton about 7 weeks following the trial, the abundance and distribution of zooplankton in the reservoir prior to application of Phoslock™ and soda ash is unknown. In addition, it is unknown to what extent food limitation versus direct toxicity of bioavailable lanthanum per se contributed to low zooplankton numbers."
Reason:

- It is highly unlikely the maximum dissolved concentration measured in any of the samples taken at Deep Creek is reflective of the concentration present uniformly in the whole water body. For this reason, many risk and exposure assessment guidance documents recommend the use of statistical representations of the data, which more effectively take into consideration the variability observed in measurements taken (enHealth 2012a, b; US EPA 1992, 2002; Frey 1993). Therefore it is inappropriate to leave this paragraph as is in the report, as it does not provide the reader with an appreciation of the uncertainty involved in using a maximum concentration.
- All-encompassing words such as "all sensitive zooplankton" should be avoided.
- The reader should be reminded of the uncertainty in attributing the perceived environmental effects at Deep Creek to the toxicity of bioavailable lanthanum from Phoslock™. This has also been discussed in previous points.
- It is also noted that in another water body (Torrens Lake), where application of Phoslock™ resulted in a maximum dissolved lanthanum concentration of 110 µg/L, surveys of macroinvertebrate communities pre- and post- application showed no substantial change in diversity and abundance (AWQC 2008). Thus the rationale that all sensitive zooplankton would be expected to die if dissolved lanthanum concentrations in water are higher than the EC50 of 43 µg/L observed in a laboratory study is not substantiated.

Decision 1.99
Variation partially approved.

NICNAS Response 1.99
This paragraph will be amended to read as: "At an exposure concentration of 220 µg/L of dissolved lanthanum in soft environmental water, most sensitive zooplankton would be expected to die within 48 hours based on the lowest measured EC50 of 43 µg La/L for water fleas in soft water from the study of Barry & Meehan (2000). While the concentration may be non-uniform, a concentration of this magnitude may be expected to show significant toxicity to sensitive species. This is consistent with environmental monitoring of Deep Creek Reservoir after application of Phoslock™ which showed almost no living

zooplankton about 7 weeks following the trial."

Request 1.100

Section 10.2.1, page 86, first paragraph

"... the observations from Deep Creek Reservoir after application of Phoslock™ indicate that environmentally toxic levels of lanthanum can persist for several weeks after application of this chemical in soft water."

Suggested change:

"... the peak measurements of dissolved lanthanum from Deep Creek Reservoir after application of Phoslock™ suggest that elevated levels of dissolved lanthanum can persist for several weeks after application of this chemical in soft water."

Reason:

- The suggested changes are more scientifically correct and explicit and reduce speculation, considering the uncertainties discussed in previous points (see Point [Request] 99).

Decision 1.100

Variation partially approved.

NICNAS Response 1.100

Statement will read as:

"... the peak measurements of dissolved lanthanum from Deep Creek Reservoir after application of Phoslock™ suggest that potential environmentally toxic elevated levels of dissolved lanthanum can persist for several weeks after application of this chemical in soft water."

Request 1.101

Section 10.2.1, page 86, second paragraph

"... removing dissolved lanthanum rapidly and irreversibly from the water column."

Suggested change:

"... removing bioavailable (i.e. ionic) lanthanum rapidly and irreversibly from the water column."

Reason:

- It is bioavailable, not necessarily dissolved lanthanum, which is potentially toxic to aquatic organisms (also see Point [Request 12] where the rationale is that the use of the term 'dissolved' interchangeably with 'bioavailable' is not appropriate, as it is well known that the filtered/dissolved concentration of metals are not necessarily a reflection of the concentrations of metal ions in solution responsible for aquatic toxicity (ANZECC 2000, pg. 7.4-2; Florence 1986; Bott 1996)).

Decision 1.101

Variation partially approved.

NICNAS Response 1.101

Statement will read as: "... removing ionic lanthanum rapidly and irreversibly from the water column."

Request 1.102

Section 10.2.1, page 86, third paragraph

"Alternative strategies such as reduced application rates with appropriate intervals between applications to allow peak levels of dissolved lanthanum to reduce may be employed."

Suggested change:

"Alternative strategies such as reduced application rates with appropriate intervals between applications to allow peak levels of dissolved lanthanum to reduce may be employed, and such

strategies seem to have succeeded in other field applications of Phoslock™ as demonstrated by much lower dissolved lanthanum levels and no demonstrable adverse environmental effects."

Reason:

- Phoslock™ Water Solutions have adopted such strategies when considering and carrying out application of Phoslock™ in a water body (see Phoslock Standard Operating Procedures supplied to NICNAS). Deep Creek was the result of abnormal dosing (three times the recommended dosing rate). Other field trials and applications where normal dosing was adhered to have had considerably lower maximum measured dissolved lanthanum levels following application (see revised Table 5.1 in Appendix). Where biological monitoring has taken place before and after a field application, no demonstrable adverse effects environmental effects were reported.

Decision 1.102

Variation partially approved.

NICNAS Response 1.102

The suggested change seems to imply that the alternative strategies would not result in significantly higher levels of dissolved lanthanum. Statement is rephrased to read as: "Alternative strategies such as reduced application rates with appropriate intervals between applications to allow peak levels of dissolved lanthanum to reduce may be employed. The applicant has reported that other field applications that have done so did not demonstrate higher than expected levels of dissolved lanthanum."

Request 1.103

Section 10.2.1, page 86, fourth paragraph

"... and several have resulted in similar maximum dissolved lanthanum concentrations."

Suggested change:

"... and several have resulted in approximately half the maximum dissolved lanthanum concentrations, which according to toxicity tests in the laboratory should have also resulted in toxicity to aquatic organisms."

Reason:

- To argue the maximum dissolved lanthanum concentrations of 220 µg/L at Deep Creek and 110 µg/L (the next highest maximum concentration observed) at Torrens Lake and Silbersee are similar would probably be inappropriate, since one is half of the other.

Decision 1.103

Variation partially approved.

NICNAS Response 1.103

Statement to read as: "... and several have also resulted in higher maximum dissolved lanthanum concentrations than those assumed in the original assessment."

Request 1.104

Section 10.3, page 86, first paragraph in section

"The environmental risks of Phoslock™ are the environmental risks of the dissolved or ionic lanthanum it contains."

Suggested change:

"The environmental risks of Phoslock™ are the environmental risks of the ionic lanthanum it contains."

Reason:

- This is more scientifically correct (see also Point [Request] 12 where it states The use of the term 'dissolved' interchangeably with 'bioavailable' is not appropriate, as it is well known that the filtered/dissolved concentration of metals are not necessarily a reflection of the concentrations of metal ions in solution responsible for aquatic toxicity (ANZECC 2000, pg.

7.4-2; Florence 1986; Bott 1996)).

Decision 1.104
Variation approved.

NICNAS Response 1.104
Text will be amended accordingly.

Request 1.105

Section 10.3.1, page 87, last sentence

"... appropriate monitoring of dissolved lanthanum levels in ..."

Suggested change:

"... appropriate monitoring of bioavailable (i.e. ionic), or alternatively dissolved, lanthanum levels in ..."

Reason:

- Bioavailable (i.e. ionic or labile) lanthanum concentrations provide a more realistic predictor of potential toxicity to aquatic organisms.
- If techniques for measurement of ionic or labile lanthanum are not readily available in the field, the alternative method of measuring dissolved lanthanum is likely to provide the closest estimate to bioavailable lanthanum.

Decision 1.105
Variation partially approved.

NICNAS Response 1.105
Last part of the paragraph to read as:
"... appropriate monitoring of bioavailable (i.e. ionic) lanthanum levels in the water and sediment compartments to ensure that levels of this toxicant remained below the revised local trigger value. If techniques for measurement of ionic or labile lanthanum are not readily available in the field, measuring dissolved lanthanum is likely to provide the closest surrogate for ionic lanthanum."

Request 1.106

Section 10.3.1, page 88, second paragraph

"To be fully effective this approach would need to be expanded to cover more taxonomic groups including sensitive benthic invertebrates, and may also include on-site microcosm or mesocosm testing as well."

Suggested change:

"To be fully effective this approach would ideally need to be expanded to cover more taxonomic groups including sensitive benthic invertebrates, and may also include on-site microcosm or mesocosm testing as well. In reality, the latter may not always be feasible due to time and resource constraints."

Reason:

- During the meeting with NICNAS (January 9th 2013), there was the acknowledgement by NICNAS attendees that the DTA's are recommendations and not required to be undertaken by all or any of the States and Territories if not deemed necessary.
- In PWS's previous interactions with Australian local and federal government bodies, it has become apparent that there are often major issues (causing public health concerns) with prolific algal blooms and potential toxins. These organisations need to act quickly to control algal blooms. However it is not always economically or time viable for a full DTA. PWS acknowledges these concerns raised by water body managers and uses this platform to express their and our concern for extensive DTA's being undertaken prior to each and every Phoslock application.

Decision 1.106
Variation partially approved.

NICNAS Response 1.106
Statement to read as:
"To be fully effective, this approach would need to be expanded to cover more taxonomic groups including sensitive benthic invertebrates and, where possible, it would be desirable to include on-site microcosm or mesocosm testing as well."

Request 1.107

Section 10.3.1, page 88, second paragraph
"These studies should also include monitoring of total and dissolved lanthanum..."
Suggested change:
"These studies should also include monitoring of total and bioavailable, or alternatively dissolved, lanthanum..."
Reason:

- See Point [Request] 105 where the rationale is that bioavailable (i.e. ionic or labile) lanthanum concentrations provide a more realistic predictor of potential toxicity to aquatic organisms.
- If techniques for measurement of ionic or labile lanthanum are not readily available in the field, the alternative method of measuring dissolved lanthanum is likely to provide the closest estimate to bioavailable lanthanum.

Decision 1.107
Variation approved.

NICNAS Response 1.107
Text will be incorporated in the report.

Request 1.108

Section 10.3.1, page 88, Table 10.1
In 'Result' column, *"No toxicity observed up to a dissolved lanthanum level of 20 µg/L (ESA, 2008)"*
Suggested change:
"No toxicity observed even at the highest dose level with a dissolved lanthanum level of 20 µg/L (ESA, 2008)"
Reason:

- As it stands, the statement reads as if toxicity was in fact observed in the study.

Decision 1.108
Variation partially approved.

NICNAS Response 1.108
Statement will read as: "No toxicity observed up to the highest dissolved lanthanum level of 20 µg/L (ESA, 2008)"

Request 1.109

Section 10.3.2, page 89, first paragraph
"... revealed a high risk of adverse effects on aquatic organisms in some application scenarios."
Suggested change:
"... revealed a possible risk of adverse effects on sensitive aquatic organisms in some application

scenarios."
Reason:
- The suggested revised RQ for acute exposure is an order of magnitude lower than that originally calculated by NICNAS (see Points [Requests] 96 and 97).
- It should be reiterated the risk of adverse effects is on sensitive organisms, as most organisms tested in the laboratory showed no adverse effects at very high application rates of Phoslock™. In addition there is considerable uncertainty in whether the dissolved lanthanum levels measured in the study on which the PNEC is based are the cause for the toxicity observed (see rationale in Point [Request] 66).

Decision 1.109
Variation partially approved.

NICNAS Response 1.109
The application conditions to minimise the risks to Phoslock™ application are mostly based on water chemistry parameters and not on species sensitivity. Statement will read as:
"... revealed a potentially high risk of adverse effects on aquatic organisms in some application scenarios."

Request 1.110
Section 10.3.2, page 89, fifth paragraph
"... dissolved or ionic lanthanum is less acutely toxic..."
Suggested change:
"... dissolved, and presumably ionic, lanthanum is less acutely toxic..."
Reason:
- Ionic lanthanum was not measured in these studies.

Decision 1.110
Variation approved.

NICNAS Response 1.110
Statement will be amended in the report.

Request 1.111
111. Section 10.3.2, page 89, sixth paragraph
"... showed lesser toxicity, possibly due to the indirect effects of the leachates on the organisms tested."

Suggested change:
"... showed lesser toxicity, possibly due to the indirect effects of the leachates on the organisms tested, or potential indirect toxicity effects of Phoslock™ granules (e.g. physical entrapment or food limitation)."
Reason:
- See Points [Request] 61 where it states that the potential secondary effect of Phoslock™ or ionic lanthanum (which binds with available CO_3 or PO_4) reducing food availability for primary consumers (e.g. macroinvertebrates) in environmental waters is a potential explanation for why ecotoxicity is observed in some laboratory experiments. However, in environmental waters, recovery of aquatic ecosystems from a disturbance, such as secondary food limitation through treatment of eutrophication, is expected to occur relatively quickly (Niemi et al. 1990, Reynolds 2002, Power 1998).
- See Point [Request] 74, where the rationale is that several studies have concluded toxicity observed may have been due to either physical (i.e. entrapment) effects of the Phoslock™ granules or food limitation due to a precipitation of Phoslock™ and phosphorus in the medium (Watson-Leung 2009, Stauber and Binet 2000, Clearwater and Hickey 2004).

Decision 1.111
Variation partially approved.

NICNAS Response 1.111
Statement to read as:
"... showed lesser toxicity, which may vary in part due to the indirect effects of the leachates on the organisms tested, or potential indirect toxicity effects of Phoslock™ granules (e.g. physical entrapment or food limitation)."

Request 1.112
Section 10.3.2, page 89, sixth paragraph
"... .EC50 of 200 mg/L Phoslock™ containing dissolved lanthanum levels of 10-14µg/L."
Suggested change:
"... .EC50 of 200 mg/L Phoslock™ containing a dissolved lanthanum level of 14 µg/L at the end of the test."
Reason:

- Table 4 in the study publication (Clearwater and Hickey 2004) indicates this was the dissolved lanthanum concentration measured at the end of the test. The concentration of 10 µg/L was measured in the lower dose of 40 mg/L Phoslock™, in which no toxicity effects were noted.

Decision 1.112
Variation approved.

NICNAS Response 1.112
This value will be amended in the report.

Request 1.113
Section 10.3.2, page 89, last paragraph
"In the presence of high levels of $CaCO_3$ (123-202 mg/L) in a chronic (10-day) sediment toxicity test, the midge Chironomus zealandicus has an EC50 of >400 mg/L Phoslock™ ..."
Suggested change:
"In the presence of high levels of CaCO3 (123-202 mg/L) in a chronic (38-day) sediment toxicity test, the midge larvae Chironomus zealandicus has an EC50 of >400 mg/L Phoslock™ ..."
Reason:

- The chronic sediment toxicity study was conducted with midge larvae (a sensitive lifestage) over 38 days, not 10 days (Clearwater 2004).

Decision 1.113
Variation approved.

NICNAS Response 1.113
This will be corrected.

Request 1.114
Section 10.3.2, page 90, first paragraph
"The apparent toxicity of the organisms may be attributed to the competition for lanthanum binding sites of the phosphate in the environmental water and sediment with the carbonate in the very hard water used in the chronic midge study."

Suggested change:
It is suggested this sentence be deleted.
Reason:
- This sentence directly follows the account of the chronic sediment toxicity test with midge larvae (Clearwater 2004). No toxicity was observed in any of the test vessels, including the highest concentration of Phoslock™ (400 mg/L), so this sentence does not make any sense.

Decision 1.114
Variation not approved.

NICNAS Response 1.114
The sentence will not be deleted but will be corrected as: "The apparent lack of toxicity of the organisms may be attributed to the competition for lanthanum binding sites of the phosphate in the environmental water and sediment with the carbonate in the very hard water used in the chronic midge study."

Request 1.115
Section 10.3.2, page 90, first paragraph
"In contrast, the water only lanthanum chloride acute (2-day) toxicity testing of the crustacean Daphnia carinata reported an EC50 of 1180 µg/L dissolved lanthanum for ASTM water (hardness 160 mg/L $CaCO_3$), where the La^{3+} could have competed with Ca^{2+} in the ASTM hard water and reduced the toxicity of dissolved lanthanum to the D. carinata. In addition, the absence of adsorbing phases such as sediment may have played a role in increasing the toxicity of the ionic lanthanum."
Suggested change:
It is suggested this passage be deleted or reworded.
Reason:
- Presumably, these tests are all being mentioned to show support for the theory that toxicity of dissolved lanthanum is reduced by hard waters in the presence or absence of dissolved organic carbon. The use of the words 'in contrast' and 'in addition' make this passage confusing to read and difficult to understand.

Decision 1.115
Variation partially approved.

NICNAS Response 1.115
Paragraph will be slightly reworded to read as:
"In contrast, the water only lanthanum chloride acute (2-day) toxicity testing of the crustacean Daphnia carinata reported an EC50 of 1180 µg/L dissolved lanthanum for ASTM water (hardness 160 mg/L $CaCO_3$), where the La^{3+} could have interacted with Ca^{2+} in the ASTM hard water and reduced the toxicity of dissolved lanthanum to the D. carinata. In addition, the absence of adsorbing phases such as sediment may have played a role in increasing the toxicity of the ionic lanthanum."

Request 1.116
Section 10.3.2, page 90, fifth paragraph
"... toxicity effects of dissolved lanthanum to aquatic organisms."
Suggested change:
"... toxicity effects of bioavailable lanthanum to aquatic organisms."
Reason:
- This is more scientifically correct.

Decision 1.116
Variation partially approved.

NICNAS Response 1.116
Statement to read as: "... toxicity effects of ionic lanthanum to aquatic organisms."

Request 1.117
Section 10.3.2., page 90, last paragraph
"... excess dissolved lanthanum and/or toxicity from dissolved lanthanum is... "
Suggested change:
"... excess dissolved lanthanum and/or toxicity from dissolved lanthanum that is bioavailable is ..."
Reason:

- This is more scientifically correct.

Decision 1.117
Variation partially approved.

NICNAS Response 1.117
Statement to read as: "... excess dissolved lanthanum and/or toxicity from dissolved lanthanum that is in ionic form is ..."

Request 1.118
Section 10.3.2, page 90, second dot point
"Ionic lanthanum remains in solution since there is a lack..."
Suggested change:
"Ionic lanthanum is more likely to remain in solution since there is a lack..."
Reason:

- There is still some uncertainty in these conclusions. This small addition helps to express this uncertainty.

Decision 1.118
Variation approved.

NICNAS Response 1.118
Amended text to be incorporated in the report.

Request 1.119
Section 10.3.2., page 91, second paragraph
"The application of Phoslock™ would result in using additional DO in decomposition of algae trapped during the flocculation process with the FRP in the water. Thus, the timing of the Phoslock™ application should not coincide with an existing algal bloom since it will put additional stress on the environmental waters limiting the availability of DO for use by other aquatic organisms."
Suggested change:
"The application of Phoslock™ would result in possible additional DO being used in decomposition of algae trapped during the flocculation process with the FRP in the water. Thus, the timing of the Phoslock™ application should ideally not coincide with an existing algal bloom since it may put additional stress on the environmental waters limiting the availability of DO for use by other aquatic organisms."
Reason:

- There is still uncertainty associated with these conclusions. The minor suggestions provide

an expression of this uncertainty.
- This comment needs to be clarified. In small water bodies, the above comment may be applicable, however in large water bodies, or those that are well oxygenated (via wind/wave action) this won't be a concern.

Decision 1.119

Variation partially approved.

NICNAS Response 1.119

Clarification will be included with the paragraph to read as: "The application of Phoslock™ would result in additional DO being used in decomposition of algae trapped during the flocculation process with the FRP in the water. Thus, the timing of the Phoslock™ application should, as far as practicable, be avoided with an existing algal bloom since it may put additional stress on the environmental waters limiting the availability of DO for use by other aquatic organisms."

Request 1.120

Section 10.3.2., page 91, last paragraph

"Rain events could also influence the release of dissolved lanthanum as observed from the field applications wherein resurfacing of the sediments resulted in increased levels of the soluble lanthanum. Phoslock™ application could be timed to not coincide with significant rain events."

Suggested delete:

"Rain events could also influence the release of dissolved lanthanum as observed from the field applications wherein resurfacing of the sediments resulted in increased levels of the soluble lanthanum. Phoslock™ application could be timed to not coincide with significant rain events."

Reason:
- While there may be some resuspension of Phoslock in shallow waters there is no evidence (or reference provided) as to where NICNAS have sourced the information for the statement "from field applications wherein resurfacing of the sediments resulted in increased levels of the soluble lanthanum".

Decision 1.120

Variation not approved.

NICNAS Response 1.120

Significant increases in lanthanum levels possibly from re-suspension of sediments were demonstrated in Torrens Lake, South Australia (pages 32–33, 35) and Hartbeespoort Dam in South Africa (page 39) which formed the basis of this finding.

Request 1.121

Section 11.3.3, page 97, third paragraph

"....porewater concentration of dissolved lanthanum is expected to be most closely correlated with toxic effects on benthic invertebrates..."

Suggested change:

"...porewater concentration of ionic lanthanum is expected to be most closely correlated with toxic effects on detritus-feeding benthic invertebrates..."

Reason:
- The toxicity of lanthanum is associated with its ionic or bioavailable form, rather than the dissolved form.
- Non-burrowing, non-detritus feeding, benthic invertebrates are unlikely to be exposed to pore water in sediment.

Decision 1.121
Variation approved.

NICNAS Response 1.121
Statement will be amended accordingly.

Request 1.122

Section 11.3.3, page 97, Table 11.2

"Testing on at least three taxonomic levels: 1 aquatic plant or algae, 2 invertebrates (1 daphnid and 1 sediment-dwelling species), and 1 fish."

Suggested change:

"Testing on at least two taxonomic levels: 2 invertebrates (1 daphnid and 1 sediment-dwelling species) and 1 fish."

Reason:

- The purpose of Phoslock™ is to limit nutrients to inhibit algal growth. It is likely the algae that will be dominant in the water body for consideration is the algae that is causing the problems (e.g. seasonal algal blooms). Limiting the nutrients available for algal growth is expected to result in reduced growth (i.e. perceived toxicity) in algae, and therefore also aquatic plants. Direct toxicity testing requirements should be limited to non-target species.

Decision 1.122
Variation not approved.

NICNAS Response 1.122
The testing requirements in Tables 11.2–11.4 of the draft report are elements of the recommendations related to the development and application of Direct Toxicity Assessments (DTAs) as presented in Chapter 8 of Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Volume 2, Aquatic Ecosystems—Rationale and Background Information ("the Guidelines"). The term "endemic" into the recommendations, related to the selection of the aquatic species to be tested, will be replaced by the phrase "locally important species or its representative" which is the terminology used in the Guidelines.

A key requirement of deriving reliable trigger values for toxicants is a clear understanding of the potential impacts on each aquatic trophic level, at a minimum. The inclusion of an aquatic plant or algae in the minimum base set of species to be tested for the effects of both ionic lanthanum and Phoslock™ is appropriate as these test organisms represent primary producers in aquatic ecosystems. The primary mode of action of both Phoslock™ and lanthanum in some environmental waters may well involve nutrient limitation, but this needs to be established through testing.

Request 1.123

Section 11.3.3, page 97, Table 11.2

"Pre- and post-application testing conducted using Phoslock™ solution in local dilution waters"

Suggested change:

"Pre- application testing conducted using Phoslock™ solution in local dilution waters. Postapplication monitoring of chemical parameters."

Reason:

- The rationale and benefits of DTA post-application have not been articulated. It is obscure how such testing would effectively aid the application of Phoslock™ such that safety for the environment was enhanced for that particular water body.

Decision 1.123
Variation partially approved.

NICNAS Response 1.123
Statement to read as:
"Pre-application direct toxicity testing of Phoslock^{TM} in local dilution waters and pre- and post- application biological and chemical monitoring of the water body."

Request 1.124
Section 11.3.3, page 98, Table 11.2
"Acute lethality test for algae or plant species;"
Suggested change:
It is suggested this be removed.
Reason:
- See rationale in Point [Request] 122.

Decision 1.124
Variation not approved.

NICNAS Response 1.124
Refer to Decision 1.22.

Request 1.125
Section 11.3.3, page 98, Table 11.3
"Testing prerequisite for softwater with low FRP"
Suggested change:
"Testing prerequisite for softwater with high FRP"
Reason:
- This is believed to be what is meant. It seems this is a transcribing error.

Decision 1.125
Variation approved.

NICNAS Response 1.125
This will be corrected.

Request 1.126
Section 11.3.3, page 98, Table 11.3
"...preferably amphipod or midge) and 1 fish species (preferably rainbow fish) that is found locally in the water body."
Suggested change:
"... preferably amphipod) and 1 fish species (preferably rainbow trout) that is found locally in the water body."
Reason:
- The available toxicity information for midges (e.g. *C. zealandicus*) and rainbow fish (i.e. *M. duboulayi*) has shown these species are relatively insensitive to Phoslock™. What would be the purpose of conducting the tests on these species?
- From the laboratory toxicity tests, the data for an amphipod (*P. helmsii*) and some of the data available for rainbow trout (*O. mykiss*) suggests these species may be more sensitive than others. Therefore shouldn't the DTA testing be recommended for these species (if they are

present in the water body)? What is the protocol if these species are not present in the water body? If these species are not present, then testing is not required?

Decision 1.126
Variation partially approved.

NICNAS Response 1.126
Comment re: midge is accepted. The fish species is not specified in the revised text, which allows a standard test species (such as rainbow trout) to be selected at the advice of the responsible water quality manager. Statement to read as: "... preferably amphipod) and 1 fish species (locally important species or its representative) that is found locally in the water body."

Request 1.127
Section 11.3.3, page 98, Table 11.3
"Pre- and post-application testing conducted using Phoslock™ solution in local dilution waters"
Suggested change:
"Pre- application testing conducted using Phoslock™ solution in local dilution waters. Postapplication monitoring of chemical parameters."
Reason:
- Refer to Point [Request] 123.

Decision 1.127
Variation partially approved.

NICNAS Response 1.127
Refer to Decision 1.123.

Request 1.128
Section 11.3.3, page 99, Table 11.4
"Testing prerequisite for softwater with low FRP"
Suggested change:
"Testing prerequisite for hardwater with any FRP"
Reason:
- This is believed to be what is meant. It seems this is a transcribing error.

Decision 1.128
Variation approved.

NICNAS Response 1.128
This will be corrected.

Request 1.129
Section 11.3.3, page 99, Table 11.4
"Testing on aquatic invertebrates (1 daphnid and 1 sediment-dwelling species, preferably amphipod or midge) endemic to the water body."
Suggested change:
"Testing on aquatic invertebrates (1 sediment-dwelling species, preferably amphipod) endemic to the water body."

Reason:

- In hard-waters, direct toxicity of Phoslock™ to daphnids has been low (Watson-Leung 2009, Lurling and Tolman 2010). In addition, in a field application to a water body (Torrens Lake), where application of Phoslock™ resulted in a maximum dissolved lanthanum concentration of 110 µg/L, surveys of macroinvertebrate communities pre- and postapplication showed no substantial change in diversity and abundance (AWQC 2008), suggesting toxicity to daphnids from these levels of dissolved lanthanum in hard water bodies does not occur. Thus there doesn't seem to be a reason for recommending to tests daphnids for hard water bodies. In this case, the hard water body DTA could be removed altogether.

Decision 1.129

Variation partially approved.

NICNAS Response 1.129

Midge will be deleted in line with response 1.126. Deletion of daphnid is not agreed. Aquatic invertebrates are consistently the most sensitive taxonomic group to adverse effects from both ionic lanthanum and Phoslock™. This group is also of concern for potential long-term effects arising from bioaccumulation of lanthanum in some species of aquatic invertebrates. The inclusion of effects testing on standard species of aquatic invertebrates, in site specific waters, would be considered an essential component of a DTA for application of Phoslock™ to a sensitive aquatic environment. Aquatic invertebrates are also of relevance as in situ biomonitors for the effects of any application of Phoslock™ to a water body with a functioning ecosystem.

Request 1.130

Section 11.3.3, page 99, Table 11.4

"Pre- and post-application testing conducted using Phoslock™ solution in local dilution waters"

Suggested change:

"Pre- application testing conducted using Phoslock™ solution in local dilution waters. Postapplication monitoring of chemical parameters."

Reason:

- Refer to Point [Request] 123.

Decision 1.130

Variation partially approved.

NICNAS Response 1.130

Refer to Decision 1.123.

Request 1.131

Section 11.3.3, page 99, Table 11.4

"Acute and/or chronic immobilisation test for daphnid;"

Suggested change:

- It is suggested this be removed.

Reason:

- See Point [Request] 129.

Decision 1.131

Variation not approved.

NICNAS Response 1.131
Refer to Decision 1.129.